

CHAPTER

2

---

**Medicare Part B drug  
payment policy issues**

---

## R E C O M M E N D A T I O N

The Congress should change Medicare's payment for Part B drugs and biologicals (products) as follows:

(1) Modify the average sales price (ASP) system in 2018 to:

- require all manufacturers of products paid under Part B to submit ASP data and impose penalties for failure to report.
- reduce wholesale acquisition cost (WAC)-based payment to WAC plus 3 percent.
- require manufacturers to pay Medicare a rebate when the ASP for their product exceeds an inflation benchmark and tie beneficiary cost sharing and the ASP add-on to the inflation-adjusted ASP.
- require the Secretary to use a common billing code to pay for a reference biologic and its biosimilars.

(2) No later than 2022, create and phase in a voluntary Drug Value Program (DVP) that must have the following elements:

- Medicare contracts with a small number of private vendors to negotiate prices for Part B products.
- Providers purchase all DVP products at the price negotiated by their selected DVP vendor.
- Medicare pays providers the DVP-negotiated price and pays vendors an administrative fee, with opportunities for shared savings.
- Beneficiaries pay lower cost sharing.
- Medicare payments under the DVP cannot exceed 100 percent of ASP.
- Vendors use tools including a formulary and, for products meeting selected criteria, binding arbitration.

(3) Upon implementation of the DVP or no later than 2022, reduce the ASP add-on under the ASP system.

**COMMISSIONER VOTES: YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0**

# Medicare Part B drug payment policy issues

## Chapter summary

Medicare Part B covers drugs that are administered by infusion or injection in physician offices and hospital outpatient departments. It also covers certain drugs furnished by suppliers. In 2015, Medicare and its beneficiaries paid about \$26 billion dollars for Part B–covered drugs and biologics. Medicare pays for most Part B–covered drugs based on the average sales price plus 6 percent (ASP + 6 percent). Since 2009, Medicare Part B drug spending has grown at an average rate of about 9 percent per year. About half of the growth in Part B drug spending from 2009 to 2013 was accounted for by price growth, which reflects increased prices for existing products and shifts in the mix of drugs, including the adoption of new drugs (Medicare Payment Advisory Commission 2015b).

Medicare Part B drug spending has been growing rapidly. Concern exists about the overall price Medicare Part B pays for drugs and the lack of price competition among drugs with similar health effects. Among the 10 products that account for the most Medicare Part B drug expenditures, 8 of those products have an annual cost per user that ranges from roughly \$10,000 to \$30,000 per year. In addition, some Part B drugs used by small numbers of beneficiaries have annual costs per user of more than \$75,000 per year. The current ASP payment system spurs price competition among generic drugs and their associated brand products by assigning these products to a single billing code. By contrast, the current ASP payment system—with most single-

## In this chapter

- Introduction
- Policy options to improve payment for Part B drugs
- Conclusion

source drugs and biologics each paid under separate billing codes—does not spur price competition among products with similar health effects. There is also concern about the financial incentives providers face under the ASP + 6 percent payment system. In particular, the 6 percent add-on to ASP may create incentives for providers to choose higher priced drugs over lower priced drugs.

The Commission's recommendation includes a set of policies that seeks to improve the current ASP payment system in the short term while developing, for the longer term, a voluntary, market-based alternative to the ASP payment system. This alternative program—which we refer to as the Part B Drug Value Program (DVP)—would allow providers to voluntarily enroll and would use private vendors to negotiate drug prices with manufacturers. The DVP would be informed by Medicare's experience with the competitive acquisition program (CAP) for Part B drugs (in effect between 2006 and 2008) but structured differently to encourage provider enrollment; give vendors greater negotiating leverage with manufacturers; and allow for providers, beneficiaries, vendors, and Medicare to share in savings achieved by the program.

It would take several years to develop and implement the DVP, but immediate action could be taken to improve the existing ASP payment system. These shorter term steps would apply to all providers and would remain in place for those providers that chose not to enroll in the DVP. Specifically, the recommended short-term actions would:

- **Improve ASP data reporting.** CMS relies on manufacturers to submit their sales data to calculate ASPs for Part B drugs, but not all manufacturers are required to report such data. Payment rates based on incompletely reported ASP data might not accurately reflect average prices. A policy requiring all Part B drug manufacturers to report ASP data and giving the Secretary the authority to apply penalties to manufacturers who do not report required data would improve the accuracy of the ASP payments.
- **Modify payment rates for drugs paid at 106 percent of wholesale acquisition cost (WAC).** Medicare generally reimburses new single-source Part B drugs at 106 percent of WAC when ASP data are not available. The WAC is the manufacturer's list price and does not incorporate prompt-pay or other discounts. A policy reducing the payment rate for drugs currently paid at 106 percent to 103 percent of WAC would reduce excessive payments for these drugs.
- **Establish an ASP inflation rebate.** Medicare's ASP + 6 percent payment rates are driven by manufacturers' pricing decisions. In theory, there is no limit on how much Medicare's ASP + 6 percent payment rate for a drug can increase

over time. An ASP inflation rebate policy would protect the Medicare program and beneficiaries from the potential for rapid price increases for individual products.

- **Establish consolidated billing codes.** The structure of the ASP payment system—with the reference biologic assigned to one billing code and its biosimilars assigned to a different billing code—does not spur price competition among these products. A policy permitting use of consolidated billing codes to group a reference biologic with its biosimilars would spur price competition among these Part B drugs.

Over the longer term, the Commission recommends that Medicare develop the DVP as a voluntary, market-based alternative to the ASP payment system for physicians and outpatient hospitals. The intent of the DVP would be to obtain lower prices for Part B drugs by permitting private vendors to use tools (such as a formulary and, in certain circumstances, binding arbitration) to negotiate prices with manufacturers and by improving incentives for provider efficiency through shared savings opportunities. Under the program, a small number of DVP vendors would negotiate prices for Part B drugs, but in contrast to the CAP, vendors would not ship products to providers. Providers that chose to enroll in the DVP would continue to buy drugs in the marketplace but at the DVP-negotiated price, and Medicare would reimburse those providers at the same negotiated price. To encourage enrollment in the DVP, providers would have shared savings opportunities through the DVP while the ASP add-on would be reduced gradually in the ASP system. Savings achieved through the DVP would also be shared with beneficiaries (through lower cost sharing) and with DVP vendors and Medicare.

The Commission's recommendation seeks to take a balanced, multipronged approach to improving payment for Part B drugs and achieving savings for taxpayers and beneficiaries. The recommendation includes policies that would improve Part B drug payment through a regulatory approach (by making reforms to the ASP payment system) and through a market-based approach (by developing a voluntary alternative DVP). The Commission's recommendation also seeks balance by including policies that would achieve savings for taxpayers and beneficiaries not just by modifying provider payment rates but also by creating pressure for drug manufacturers to reduce or slow the growth of drug prices (e.g., through consolidated billing codes, an ASP inflation rebate, and DVP vendor tools such as a formulary and binding arbitration). ■



---

## Introduction

---

Medicare Part B covers drugs that are administered by infusion or injection in physician offices and hospital outpatient departments (HOPDs).<sup>1</sup> Medicare Part B also covers certain other drugs provided by pharmacies and suppliers (e.g., inhalation drugs and certain oral anticancer, oral antiemetic, and immunosuppressive drugs). In 2015, Medicare and its beneficiaries paid about \$26 billion dollars for Part B–covered drugs and biologics.

In accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Medicare pays physicians and suppliers for most Part B–covered drugs based on the average sales price plus 6 percent (ASP + 6 percent).<sup>2</sup> Medicare payment for separately payable Part B drugs reimbursed through the hospital outpatient prospective payment system (OPPS) is generally under the discretion of CMS, which established a rate of ASP + 6 percent. Low-cost drugs and certain other drugs are bundled, or “packaged,” into payment for other services under the OPPS instead of being paid separately.<sup>3</sup> Like other Medicare services, Part B–covered drugs are subject to the budget sequester effective April 1, 2013, through 2025.<sup>4</sup> In this chapter, we use the term *drug* to refer to both drugs and biologics (unless otherwise noted).<sup>5</sup>

In addition to a payment of ASP + 6 percent for a Part B–covered drug, Medicare makes a separate payment under the physician fee schedule or OPPS to the physician or hospital administering the drug (that is, for the act of injecting or infusing the product into the patient). We estimate that, in 2015, Medicare and its beneficiaries paid about \$3.6 billion for drug administration services.<sup>6</sup> Medicare also pays a dispensing or supplying fee to suppliers (typically pharmacies) that dispense (to beneficiaries) inhalation drugs and oral anticancer, oral antiemetic, and immunosuppressive drugs and pays a furnishing fee to providers of clotting factor. In June 2016, the Commission recommended that CMS reduce the dispensing and supplying fees paid to pharmacies to be similar to those of other payers. This chapter includes data only on the ASP + 6 percent payments and not on drug administration payments or supplying and dispensing fees (unless otherwise noted).

Medicare spending on Part B drugs is substantial and has grown rapidly in recent years. In 2015, total Part B drug spending amounted to about \$26 billion, with

about \$21 billion in program payments and \$5 billion in beneficiary cost sharing.<sup>7</sup> Of that spending, physician offices accounted for about \$15 billion; HOPDs, about \$9 billion; and suppliers, about \$2 billion. In 2015, Medicare spending on Part B–covered drugs increased 13 percent over the prior year.<sup>8</sup> Since 2009, Medicare Part B drug spending grew at an average rate of about 9 percent per year. About half of that growth in Part B drug spending between 2009 and 2013 was accounted for by price growth, which reflects increased prices for existing products and shifts in the mix of drugs, including the adoption of new drugs (Medicare Payment Advisory Commission 2016a).

In recent years, total Medicare Part B drug spending has grown more rapidly in HOPDs compared with physician offices and suppliers. Between 2009 and 2015, average annual growth was roughly 16 percent for HOPDs and 7 percent for physicians. Over half of the Medicare Part B drug spending in HOPDs in 2015 was attributable to hospitals that participate in the 340B Drug Pricing Program. Nonprofit hospitals that qualify for the 340B Drug Pricing Program receive substantial discounts on Part B drugs.<sup>9</sup>

Medicare Part B covers a wide range of drugs. Some of the most commonly used Part B drugs like corticosteroids, saline, and vitamin B-12 are inexpensive, with an ASP per administration of less than \$10. In contrast, the top 10 drugs that accounted for the largest share of Part B spending in 2015 are more expensive, ranging from roughly \$1,000 to \$6,000 per administration and from roughly \$2,000 to \$32,000 per beneficiary per year (Table 2-1, p. 38). Among these top 10 products in 2015, 8 were biologics and none faced biosimilar or generic competition. Beyond these products, additional Part B drugs that have annual costs of more than \$75,000 per year are used by small numbers of beneficiaries. In 2015, biological products (not including vaccines) accounted for the majority of Part B drug spending (65 percent). Small-molecule drugs accounted for about 24 percent of Part B drug spending, with roughly half of that spending on single-source drugs without generic competition (15 percent) and on drugs with generic competition (10 percent). The remainder of Part B drug spending is accounted for by vaccines, radiopharmaceuticals, products that are regulated as devices (e.g., certain injections for knee pain), and products billed under not-otherwise-classified codes.

**TABLE  
2-1**

**Top 10 Part B-covered drugs paid based on ASP by total expenditures and by number of beneficiaries who used the drug, 2015**

HCPCS code	Drug name	Common indication or type of drug	Total Medicare payments (in billions)	Number of beneficiaries who used drug (in thousands)	Average ASP + 6 percent payment	
					Per administration	Per beneficiary
J0178	Aflibercept	Macular degeneration	\$1.8	180	\$2,100	\$10,000
J9310	Rituximab	Cancer, RA	1.6	68	5,800	22,800
J2505	Pegfilgrastim	Cancer supportive	1.3	97	3,600	12,800
J1745	Infliximab	RA	1.2	58	3,700	21,200
J2778	Ranibizumab	Macular degeneration	1.2	120	2,000	9,500
J9035	Bevacizumab	Cancer, macular degeneration	1.1	208	1,100	4,100
J0897	Denosumab	Osteoporosis, cancer supportive	0.9	354	1,200	2,400
J9355	Trastuzumab	Cancer	0.6	20	3,200	32,400
J9305	Pemetrexed	Cancer	0.5	22	5,500	24,900
J9041	Bortezomib	Cancer	0.5	21	1,500	24,000

Note: ASP (average sales price), HCPCS (Healthcare Common Procedure Coding System), RA (rheumatoid arthritis). Eight of these top 10 high-expenditure products are biologics; pemetrexed and bortezomib are the only drugs in the top 10. Total Medicare payments include the effect of the sequester. Average ASP + 6 percent payment amount per administration and per beneficiary are calculated at the drug billing-code level and do not include the effect of the sequester. These averages are calculated after removing extreme values from the data (i.e., values that are less than the 1st percentile and greater than the 99th percentile for the HCPCS code). Critical access hospitals and other hospitals not paid under the outpatient prospective payment system are excluded from the analysis. Data for beneficiaries with Medicare as a secondary payer are excluded from the analysis. Vaccines paid 95 percent of the average wholesale price are also excluded (e.g., Prevnar 13, a pneumococcal vaccine, for which Medicare paid about \$0.9 billion in 2015).

Source: MedPAC analysis of Medicare claims data for physicians, outpatient hospitals, and suppliers.

### Medicare’s payment methodology for Part B drugs

Medicare pays for most Part B-covered drugs based on ASP + 6 percent. The ASP for a drug reflects the average price realized by the manufacturer for its sales broadly across different types of purchasers and for patients with different types of insurance coverage. It is based on the manufacturer’s sales to all purchasers (with certain exceptions) net of manufacturer rebates, discounts, and price concessions.<sup>10</sup> Medicare pays providers ASP + 6 percent for the drug regardless of the price a provider pays for the drug. Manufacturers report ASP data to CMS. The Medicare Part B drug payment rates are updated quarterly. There is a two-quarter lag in the data used to set ASP + 6 percent payment rates.

Payments for single-source drugs and biologics, multiple-source drugs, and biosimilars are set differently. Each single-source drug and biologic is paid under its own billing code at a rate equal to 106 percent of its own ASP. For multiple-source drugs, both the brand and generic versions are paid under a single billing code at the same

rate (i.e., 106 percent of the weighted average ASP for all products assigned to that code). All biosimilars associated with the same reference product are paid under a single billing code at the same rate (i.e., 100 percent of the weighted average ASP for the biosimilars plus 6 percent of the reference biologic’s ASP). The reference biologic remains under its own billing code and is paid 106 percent of its own ASP.

An individual provider may purchase a drug for more or less than ASP for a number of reasons. ASP is the average price from the manufacturer’s perspective. Generally, some purchasers pay more than ASP and some pay less. For example, prices can vary across purchasers of different sizes (e.g., due to volume discounts) or across types of purchasers (e.g., physicians, hospitals, and pharmacies). In addition, the two-quarter lag in ASP data can result in the average provider acquisition cost for a drug being different from the ASP used to set the Medicare payment amount for a quarter. When prices increase or decrease, it takes two quarters before that price change is reflected in the ASP data used to pay providers.<sup>11</sup>



In our June 2016 report to the Congress, we analyzed proprietary data from IMS Health Incorporated on invoice prices for 34 high-expenditure drugs for clinic purchasers to get a sense of how providers' acquisition costs for drugs compare with ASP.<sup>12</sup> This analysis found that, for two-thirds of the 34 drugs, at least 75 percent of the volume was sold to clinics at an invoice price of less than 102 percent of ASP in the first quarter of 2015 (Medicare Payment Advisory Commission 2016a). The analysis also found that the median across the 34 drugs of the 75th percentile invoice price as a percent of ASP declined in the second quarter of 2013 when the sequester went into effect (from around 103 percent of ASP in the first quarter of 2012 through the first quarter of 2013 to about 101.5 percent of ASP in the second quarter of 2013 through the second quarter of 2015). These data suggest that some manufacturers may have responded to the sequester by changing their pricing patterns in a way that mitigated the effect of the sequester for some providers (Medicare Payment Advisory Commission 2016a).

### **Broader context affecting Medicare Part B drug spending**

The Part B drug payment system is based on the manufacturer's ASP for drugs, a manufacturer price that reflects sales to many purchasers and encompasses patients with many types of insurance. It is important to recognize that Medicare exists within a U.S. health care environment that involves a broad mix of not only public and private payers and local provider markets but also federal and state laws, agencies, and policies. These external environmental factors have a significant influence on the prices Medicare pays for drugs.

The federal government, through the Patent and Trademark Office and the Food and Drug Administration (FDA), grants temporary monopolies to pharmaceutical companies in the form of patents and data and marketing "exclusivity" for a period during which generic drugs and biosimilars are unable to enter the market. Laws such as the Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the Hatch-Waxman Act) and the Biologics Price Competition and Innovation Act of 2009 (enacted as part of the Patient Protection and Affordable Care Act of 2010) lay out processes by which manufacturers may market approved drugs and biologics without entry of competitors. Patents and periods of exclusivity provide a financial incentive for innovation by permitting the innovator to price products higher than if there were free entry of competitors. Patents are awarded for 20 years, and FDA approval to market

a therapy triggers a period of 5 years of exclusivity for small-molecule drugs, a 12-year period for biologics, and a 7-year period for drugs and biologics receiving orphan drug designation for specific indications. The length of a drug's effective market protection depends on when the developer received a patent, how long the developer takes to assemble evidence on safety and effectiveness, and how long the FDA takes to evaluate that evidence. In addition, there are legal processes that affect how and when competitors may challenge manufacturers' market protection.

Law and FDA regulations describe the process for approving drugs and biologics, evidentiary standards for approval, and rules about the indications for and processes by which the drug can be marketed (e.g., through direct-to-consumer advertising). The FDA's processes for reviewing applications and the speed at which it does so directly affect the number of medicines available on the market, as do whether and how many therapeutic substitutes and generics are available within a drug class. With respect to biosimilars, FDA guidance on a range of issues (including standards for FDA approval of biosimilars, the naming convention for biosimilars, and proposed standards for demonstrating interchangeability) has implications for the resources involved in obtaining FDA approval, the availability of biosimilars, and clinician attitudes about the safety and efficacy of these products, which in turn can affect the competitive environment and pricing of these products.

Other external factors that can affect Medicare drug spending include biomedical research and development and the policies of other government programs. For example, biomedical research and development funding through the National Institutes of Health and government tax credits for drug research and experimentation can affect the amount of new drug products available and the diseases they target. The Medicaid "best price" policy, which requires makers of innovator drugs to provide a rebate equal to the greater of 23.1 percent of the average manufacturer price (AMP) or the difference between AMP and the manufacturer's "best price" to any customer (with certain exceptions), can increase costs to other payers, including Medicare (Congressional Budget Office 1996).

When the Commission considers payment adequacy for most types of services, it uses a framework that includes looking at providers' profit margins. Drug manufacturers are not Medicare providers since Medicare does not pay them directly for drugs. Nonetheless, drug manufacturers'

financial performance provides broader context when considering payment changes for Part B drugs. According to an analysis by Pembroke Consulting, the 11 U.S. drug manufacturers with revenues large enough to be on the 2016 Fortune 500 list had a profit margin as a share of revenues of 22.3 percent on average and 17.3 percent at the median (Fein 2016).<sup>13</sup> These margins reflect net revenues after expenses on research and development, general administration and marketing, and income taxes. Another measure of profitability is return on assets (ROA), which is profit margin as a share of average total assets. Pembroke Consulting estimated that for the same group of drug manufacturers, the ROA was 10.7 percent on average and 7.8 percent at the median.<sup>14</sup> The level of drug prices and profits needed to fund an appropriate amount of drug research and development is a controversial issue. On the one hand, some argue that the riskiness and cost of the drug development process necessitates substantial profit margins to draw in capital investment and spur innovation. Some stakeholders point to a report by Deloitte indicating that the projected rate of return on new drugs and biologics in the late-stage pipeline for 12 large drug manufacturers has declined in recent years (Deloitte 2016). On the other hand, the Deloitte report also suggests that some inefficiencies exist in the research and development process and states that “opportunities to reduce costs exist, in clinical trials, during discovery and in other areas of development...” The Deloitte report also concludes that companies “can improve R&D [research and development] efficiency, regardless of scale.” In addition, a recent analysis by Yu and colleagues (2017) disputes the contention made by drug manufacturers that higher prices in the United States compared with other countries are necessary to fund drug research and development. For a group of manufacturers, Yu and colleagues estimate that the additional revenue generated by the difference in prices between the United States and other countries substantially exceeds global research and development spending.<sup>15</sup>

---

## Policy options to improve payment for Part B drugs

---

Medicare’s ASP + 6 percent payment methodology for Part B drugs has raised several concerns. There is concern about the overall price Medicare Part B pays for drugs and the lack of price competition among drugs with similar health effects. There is also concern about the financial incentives providers face under the ASP payment system. In particular, the 6 percent add-on to ASP may create

incentives for providers to choose higher priced drugs over lower priced drugs.<sup>16</sup>

This chapter discusses policies that seek to improve payment for Part B drugs. The recommendation’s set of policies would improve the current ASP payment system in the short-term while developing an alternative voluntary program that providers could choose to enroll in instead of remaining in the ASP system. (See Figure 2-1 for an overview of the set of recommended policies.) This alternative program—which we refer to as the Part B Drug Value Program (DVP)—would be informed by Medicare’s past experience with the competitive acquisition program (CAP) for Part B drugs, but structured differently to encourage provider enrollment; give vendors greater negotiating leverage with manufacturers; and allow for providers, beneficiaries, vendors, and Medicare to share in savings achieved by the program.

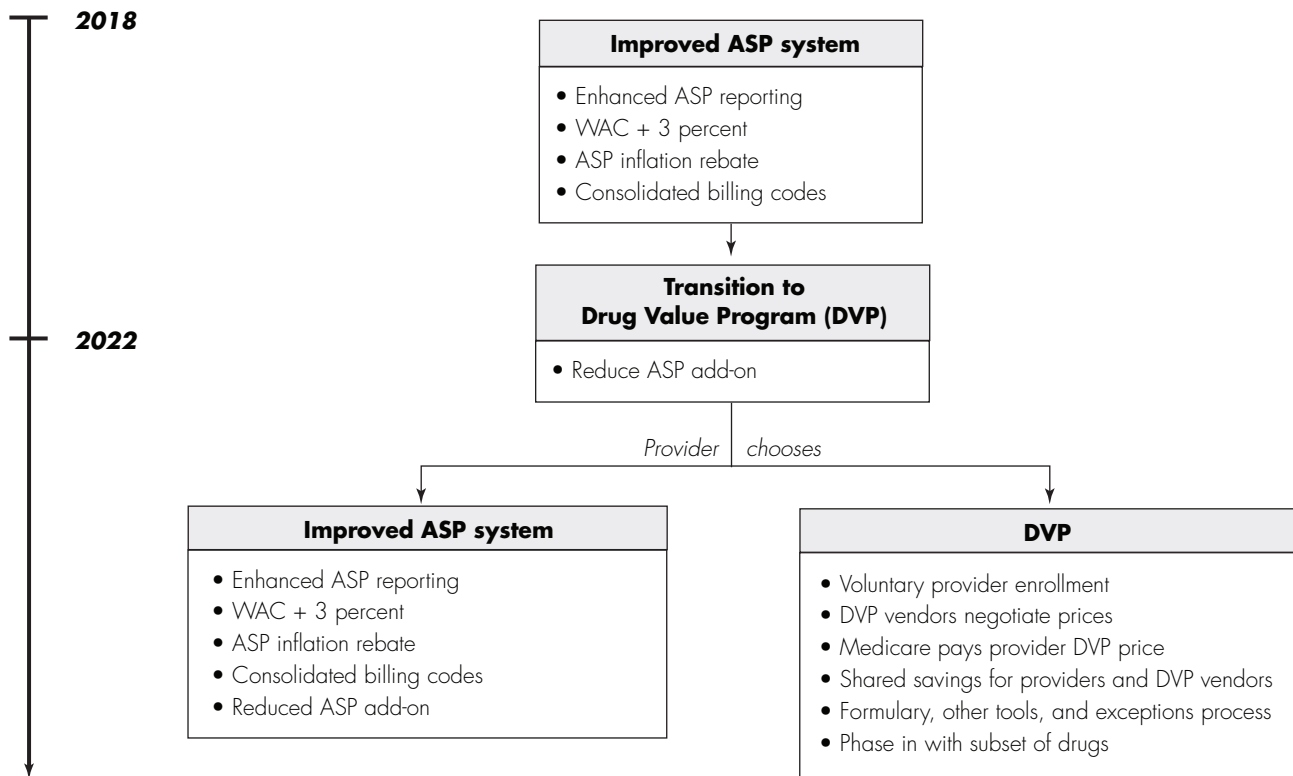
While it would take several years for the DVP to be developed and operationalized, immediate action could improve the existing ASP payment system. These payment policy improvements would apply in the short run to all providers and would remain in place for those providers that chose not to enroll in the DVP once that program became operational. Our recommendation includes the following actions:

- improve ASP data reporting by requiring all manufacturers of Part B drugs to report ASP data and impose civil monetary penalties for failure to report;
- modify payment rates for drugs currently paid at 106 percent of wholesale acquisition cost (WAC) to 103 percent of WAC to reduce overpayments;
- implement an ASP inflation rebate as protection against the potential for rapid price increases by manufacturers; and
- use consolidated billing codes to pay for Part B products with a reference biologic and its associated biosimilars to spur price competition.

The DVP would be a voluntary, market-based alternative to the ASP payment system for physicians and HOPDs. The intent of the DVP would be to obtain lower prices for Part B drugs by permitting private vendors to use tools (such as a formulary) to negotiate with manufacturers and improve incentives for provider efficiency through shared savings opportunities. Under the program, a small number of DVP vendors would negotiate prices for Part B drugs, but vendors would not ship product to providers.

**FIGURE 2-1**

**Set of Commission’s recommended policies for Part B drugs**



Note: ASP (average sales price), WAC (wholesale acquisition cost).

Providers that chose to enroll in the DVP would continue to buy drugs in the marketplace but at the DVP-negotiated price, and Medicare would reimburse those providers at the same negotiated price. To encourage enrollment in the DVP, providers would have shared savings opportunities through the DVP while the ASP add-on would be reduced gradually in the ASP system. Savings achieved through the DVP would also be shared with beneficiaries through lower cost sharing and with DVP vendors and Medicare.

We note that some stakeholders raise concerns that one or more of these policies aimed at reducing Medicare spending for Part B drugs would reduce incentives for innovation. While arguments can be made that any effort to reduce drug prices lessens incentives for innovation, there is an inherent need to strike a balance between incentives for innovation and affordability and access. A presumption of arguments against reducing drug prices is that current prices strike the appropriate balance. However,

others argue that the current level of prices for some products adversely affect affordability and access and exceed what is necessary to provide appropriate incentives for innovation (Nichols 2015).

**Improving ASP data reporting**

ASP data reporting could be improved by requiring all manufacturers of Part B drugs to report ASP data and by imposing civil monetary penalties for failure to report. Such actions could help ensure the accuracy of CMS’s drug prices. CMS relies on manufacturers to submit their sales data to calculate ASPs for Part B drugs, but not all manufacturers are required to report such data. Specifically, Section 1927(b)(3) of the Social Security Act requires manufacturers with Medicaid rebate agreements in place to report the ASP and number of units sold for each of their Part B drugs on a quarterly basis. If manufacturers covered by this section do not report data

within 30 days after the end of the quarter, they face civil monetary penalties of up to \$10,000 for each day the data are not provided and, after 90 days of the deadline imposed, suspension of their rebate agreements. However, because not all manufacturers of Part B drugs have Medicaid rebate agreements in place, not all manufacturers that sell Part B drugs are required to submit ASP data.

The Health and Human Services Office of Inspector General (OIG) has found that a number of Part B drug manufacturers are not required to report their ASP data. For example, OIG found that at least 45 manufacturers were not required to report ASPs for 443 Part B national drug codes (NDCs) in the third quarter of 2012 (Office of Inspector General 2014). In that quarter, only about half (22) of these manufacturers voluntarily reported ASP data. OIG noted multiple reasons why a manufacturer might not have a Medicaid rebate agreement in place and, therefore, not be required to submit ASP data. For example, manufacturers of Part B drugs that are considered devices by Medicaid and the FDA (e.g., certain injections for knee pain) typically do not have rebate agreements. Many repackagers—entities that purchase drugs from manufacturers and resell the drugs in smaller package sizes—also do not have Medicaid rebate agreements.

OIG has also reported that some manufacturers that are required to submit ASP data fail to do so. For example, OIG found that at least 207 manufacturers of Part B drugs had a Medicaid rebate in place in the third quarter of 2012 and that at least 74 of these manufacturers did not report ASPs for at least one of their Part B NDCs (Office of Inspector General 2014). While most manufacturers failed to submit data for a small share of their NDCs or a small number of NDCs, OIG has initiated actions against certain manufacturers that failed to satisfy their submission requirements. These findings suggest the importance not only of requiring manufacturers to report ASP data but also of giving the Secretary the necessary authority to enforce compliance.

Failing to report ASPs can impact prices for Part B drugs in several ways. For drugs with partially complete ASP data—that is, drugs for which some manufacturers report ASPs but others do not—payment rates based on only the reported ASP data might not reflect average prices of all manufacturers accurately. For drugs with no ASP data—that is, drugs for which no manufacturer reports ASPs—CMS might resort to pricing drugs using alternative and potentially inflated measures of price such as WACs.

Requiring that all manufacturers of Part B drugs report ASP data would improve the accuracy of CMS's drug prices and help prevent CMS from relying on other, less appropriate prices, such as WACs.<sup>17,18</sup> Enhancing the monetary penalty for failing to report ASP data—for instance, from \$10,000 to \$50,000 per day—and maintaining the ability to exclude a drug from coverage after 90 days of failing to report could help improve the timeliness of ASP data. Repackagers could be excluded from the reporting requirement. This exclusion would reduce the administrative burden of this policy (since many repackagers currently do not report ASP data), avoid double-counting sales (since the same drug can be sold multiple times as it moves through the supply chain), and provide an incentive for manufacturers to find the most efficient way for their drugs to reach consumers (since any mark-up by repackagers would not be included in the ASP).<sup>19</sup>

While this policy requires enhanced reporting of ASP data, it does not call for additional checks on the data that manufacturers report. Ensuring the quality of ASP data is important because lapses in the quality of the data, such as inappropriately included or excluded costs, can affect the accuracy of CMS's drug prices. For example, variation in what manufacturers consider bona fide service fees could affect ASPs. The Secretary could consider providing additional guidance to clarify reporting requirements and enhanced oversight of data submissions to ensure proper compliance. The Commission could also consider examining this issue in the future.

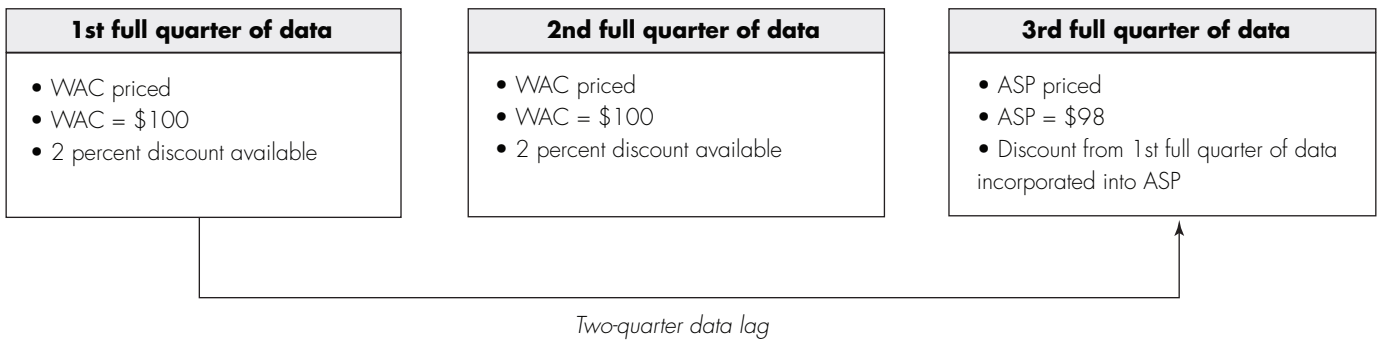
### **Modifying payment rates for drugs paid at 106 percent of wholesale acquisition cost**

The Commission supports reducing the payment rate for drugs currently paid at 106 percent of WAC to 103 percent of WAC. The intent is to reduce the excessive payments made when a drug is priced based on its WAC since the same drug is often paid at a higher rate when WAC priced compared with ASP priced because discounts are not incorporated into WAC-based prices.

The Commission has questioned whether Medicare should pay for certain Part B drugs at 106 percent of WAC. Medicare generally reimburses Part B drugs at 106 percent of WAC when ASP data are not available.<sup>20</sup> For example, when a new, single-source drug or the first biosimilar to a reference product enters the market, an ASP may not be available for nearly three calendar quarters in order to allow time for manufacturers to report sales data and CMS

**FIGURE  
2-2**

**Illustrative example of how a 2 percent discount available while a drug is WAC priced is incorporated into its ASP**



Note: WAC (wholesale acquisition cost), ASP (average sales price).

Source: MedPAC analysis of CMS payment policies.

to calculate an ASP. For new drugs, an ASP is calculated based on the first full quarter of data available, with a two-quarter lag. For example, if a new drug was first sold in February, the first full quarter would be that year's second quarter (April through June). The data for this quarter would then be used to calculate the rates for the fourth quarter, beginning October 1. In this example, providers would be paid at 106 percent of WAC from February through the end of September.

The WAC is the manufacturer's list price for a drug paid by wholesalers or direct purchasers in the United States. While manufacturers might be influenced by various outside factors—such as physician preference, the price of similar drugs, or potentially negative public reactions—setting a drug's WAC is ultimately controlled by the manufacturer. Unlike an ASP, a drug's WAC does not incorporate prompt-pay or other discounts. Prompt-pay discounts have been reported by industry stakeholders to be in the range of 1 percent to 2 percent of the drug's purchase price. If discounts are available on drugs reimbursed by Medicare at 106 percent of WAC, then Medicare is paying more for drugs than it otherwise would under the ASP-based formula. Furthermore, because beneficiaries are liable for 20 percent cost sharing on Part B drugs, beneficiaries incur these extra costs also.

Because the data used to set ASPs have a two-quarter lag, a drug's initial ASP is based on sales data from when a drug was reimbursed using its WAC. Therefore, a drop

in price from when a drug was priced using its WAC to when a drug was priced using its ASP could indicate the presence of discounts that were not reflected in its WAC (Figure 2-2). To examine the extent of discounts on drugs reimbursed at 106 percent of WAC, we tracked the price of eight new, high-expenditure Part B drugs before and after the drugs were priced using ASPs.<sup>21</sup> Specifically, we identified a drug's WAC using First Databank and compared that price with the price CMS posted on the agency's quarterly ASP drug pricing files for a year after the drug first appeared on the pricing files.<sup>22</sup> Observing drugs over this period allows time for rebates, to the extent there were any, to begin to be incorporated into a drug's ASP since certain rebates can be lagged.

We found that drugs' ASPs one year after appearing on CMS's drug pricing files were generally lower than their WACs, suggesting that drug purchasers received discounts that were not incorporated into WACs. Namely, the ASP one year after appearing on CMS's drug pricing files was lower than the WAC for seven out of the eight drugs we examined, with aflibercept's price experiencing no movement. For these seven drugs, the price declines ranged from 0.7 percent to 2.7 percent (Table 2-2, p. 44).

While the differences between WAC and ASP payment rates for the cohort of new, high-expenditure drugs appear to be modest during our study period, larger differences occur in other instances in which WAC-based payment rates are used. First, CMS may revert to pricing drugs

**TABLE  
2-2**

**Price declines from drugs' initial WACs to ASPs suggest modest discounts commonly available while drugs are WAC priced**

Drug	Percentage change in price
Abatacept	-2.1%
Aflibercept	0.0
Bendamustine	-2.7
Denosumab	-0.7
Ipilimumab	-1.6
Natalizumab	-2.7
Paclitaxel protein bound	-1.2
Ranibizumab	-1.8

Note: WAC (wholesale acquisition cost), ASP (average sales price). Percentage change in price determined from a drug's initial WAC to its ASP one year after being listed in CMS's ASP drug pricing files. Although initially approved by the Food and Drug Administration (FDA) in November 2004, natalizumab's manufacturer suspended marketing of the drug in 2005. In June 2006, the FDA approved an application for resumed marketing of the drug. For the purposes of calculating the change in price, we treat natalizumab as though it were approved in June 2006.

Source: MedPAC analysis of data from Medicare claims, CMS's ASP drug pricing files, and First Databank.

based on WACs instead of ASPs in instances when manufacturers do not report data or when other data issues exist. In a 2014 report, OIG found three instances in the first quarter of 2013 in which CMS priced a Part B drug using WACs because of such issues (Office of Inspector General 2014). While the ASP for these drugs was not known, OIG found that WACs often do not reflect actual market prices for drugs.<sup>23</sup> Second, while the number of biosimilars is limited, early patterns suggest that large discounts on biosimilars may be available while those drugs are WAC priced.<sup>24</sup> For example, applying the same methodology used to examine our cohort of new, high-expenditure drugs, we found that the price of Zarxio, the first biosimilar approved in the United States, declined by approximately 16 percent within one year of being listed on CMS's drug pricing files in the fourth quarter of 2015.

Based on industry statements regarding the magnitude of prompt-pay discounts, our analysis of a small group of new drugs, and previous OIG research, the Commission supports reducing the payment rate for drugs currently paid at 106 percent of WAC by 3 percentage points—

roughly the high end of the discounts we observed. In doing so, many new, WAC-priced drugs would be paid the same or less than if they were ASP priced, assuming that manufacturers would not substantially increase discounts in the future. Further, to maintain parity between WAC-priced and ASP-priced drugs, the payment rate for WAC-priced drugs could be further reduced if changes were made to ASP-priced drugs. For example, if the payment rate for ASP-priced drugs were reduced by 3 percentage points, the payment rate for WAC-priced drugs could be reduced to 100 percent of WAC (i.e., 103 percent minus 3 percentage points). Both the initial reduction of 3 percentage points and further reducing the add-on if the ASP add-on is reduced would help maintain parity between ASP-based prices and WAC-based prices and would be consistent with the Commission's policy of paying similar rates for similar care.

This policy does not address drugs for which WACs substantially exceed ASPs, such as biosimilars and drugs for which CMS substitutes WAC-based prices for ASP-based prices because of a lack of data. Other policies the Commission supports—consolidated billing codes for biosimilars and reference products and improved ASP data reporting—could help address these issues.

**ASP inflation limit**

To protect taxpayers and Medicare beneficiaries from substantial price increases over time for individual drug products, the Commission supports requiring drug manufacturers to pay Medicare a rebate when a Part B drug product's ASP grows faster than an inflation benchmark. Elements of such a policy would include tying beneficiary cost sharing and provider add-on payments to the inflation-adjusted ASP and exempting low-cost drugs and certain utilization from rebates. While the Commission has pursued a rebate approach, we also discuss an alternative approach that could be used to limit growth in Medicare's ASP + 6 percent payment rates.

Under Medicare's ASP payment system, growth in Medicare's ASP + 6 percent payment rates for individual drugs is driven by manufacturer pricing policies.<sup>25</sup> In theory, there is no limit on how much Medicare's ASP + 6 percent payment rate for an individual drug can increase over time. Table 2-3 shows ASP growth between January 2005 and January 2017 for the 20 Part B drugs with the highest 2015 expenditures. Among these 20 high-expenditure drugs, the median ASP growth rate was slightly below inflation as measured by the consumer

**TABLE  
2-3**

**Growth in ASP for the 20 highest expenditure Part B drugs, 2005-2017**

HCPCS code	Drug name	Total Medicare payments in 2015 (in billions)	Average annual ASP growth, from January to January of each year				Earliest year of ASP data if not 2005
			2005-2017	2005-2010	2010-2016	2016-2017	
J0178	Aflibercept	\$1.8	0.0%*	N/A	0.0%*	0.0%	2013
J9310	Rituximab	1.6	5.3	5.0%	5.3	6.4	
J2505	Pegfilgrastim	1.3	5.1	0.8	8.4	7.6	
J1745	Infliximab	1.2	3.7	2.0	5.3	2.9	
J2778	Ranibizumab	1.2	-0.7*	-0.2*	-0.7	-1.9	2008
J9035	Bevacizumab	1.1	2.2	0.1	3.6	4.1	
J0897	Denosumab	0.9	2.7*	N/A	1.8*	6.6	2012
J9355	Trastuzumab	0.6	4.9	4.1	5.5	5.6	
J9305	Pemetrexed	0.5	3.9	4.5	3.4	3.3	
J9041	Bortezomib	0.5	4.2	6.1	3.4	-1.2	
J0129	Abatacept	0.5	9.4*	1.4*	12.4	16.3	2007
J2353	Octreotide depot	0.4	6.1	4.9	6.6	10.0	
J9033	Bendamustine	0.3	5.2*	-0.6*	4.8	13.8	2009
J0881	Darbepoetin alfa	0.3	0.7	-4.4	6.6	-7.2	
J0885	Epoetin alfa	0.3	1.3	-2.1	4.4	-0.1	
J2323	Natalizumab	0.3	10.7*	4.7*	12.9	10.3	2008
J1561	Gamunex-C and Gammaked	0.3	1.1*	7.0*	1.8	-12.7	2008
J9264	Paclitaxel protein bound	0.3	2.0*	3.0*	1.1	3.2	2006
J9217	Leuprolide acetate	0.3	-1.1	-4.0	3.4	-12.5	
J2357	Omalizumab	0.3	6.4	4.6	7.7	8.0	
Median average annual ASP growth across top 20 drugs			3.8	2.5	4.6	3.7	
Consumer price index for urban consumers			2.0	2.6	1.5	2.5	

Note: ASP (average sales price), HCPCS (Healthcare Common Procedure Coding System), N/A (not applicable). "Medicare payments" include Medicare program payments and beneficiary cost sharing and include the effect of the sequester and exclude critical access hospitals and other hospitals not paid under the outpatient prospective payment system. Vaccines paid 95 percent of the average wholesale price are also excluded (e.g., Prevnar 13, a pneumococcal vaccine, for which Medicare paid about \$0.9 billion in 2015).

\*Indicates that ASP payment rates were not available for the full period listed, and the average annual growth rate was calculated based on the earliest January for which data were available.

Source: MedPAC analysis of CMS ASP pricing files and consumer price index for all urban consumers data from the Bureau of Labor Statistics and Medicare claims data for physicians, outpatient hospitals, and suppliers.

price index for urban consumers (CPI-U) from 2005 to 2010 and has exceeded inflation since 2010. Some drugs experienced higher ASP growth than others. For example, over the course of the ASP payment system (from 2005 to 2017), ASPs for several high-expenditure drugs have grown at an average annual rate of roughly 5 percent or more (i.e., natalizumab, abatacept, omalizumab, octreotide depot, rituximab, bendamustine, pegfilgrastim, and trastuzumab). In the last year (January 2016 to January 2017), 9 of the top

20 high-expenditure drugs had ASP growth of 5 percent or more, and 4 of the products had ASP growth of 10 percent or more.

Among products outside the top 20 highest expenditure drugs, a number of Part B drugs experienced substantial price increases. For products with at least \$5 million in Medicare spending in 2015, 17 products experienced an increase in their ASP of 100 percent or more between

January 2010 and January 2017.<sup>26</sup> For example, over this period, several products—injectable cyclophosphamide, vitamin B-12, mitomycin, and pegloticase—had very large ASP increases ranging from 500 percent to 1,400 percent, and one product—edetate calcium disodium—had an ASP increase of over 6,000 percent. A variety of factors may contribute to price increases. For example, with some of these products, price increases occurred when only one manufacturer made the product, when the product changed ownership, when a competing product experienced a shortage, or when the product itself was in short supply due to production problems or difficulty obtaining raw ingredients.

A policy could be instituted to limit the amount that Medicare’s ASP + 6 percent payment for a product can grow over time. Such a limit would protect the Medicare program and beneficiaries from the possibility that a manufacturer could institute a dramatic price increase and would generate savings for existing drugs that experience ASP growth higher than a specified inflation threshold. It would not, however, address the issue of high launch prices for new products, and it might spur some manufacturers to set higher launch prices.

Some argue that an administrative constraint on price growth is contrary to letting market conditions and competitive forces drive payments for Part B drugs; however, in many instances, a competitive market does not exist for Part B drugs. The federal government grants temporary monopolies to pharmaceutical companies in the form of patents as well as data and marketing “exclusivity” for a period of time. During these periods, manufacturers have substantial market power to set prices without the potential for another company to enter the market and sell the same product at a lower price. Although, in some cases, drugs with patent protection may face competition from other brand drugs in the same therapeutic class, price competition between such products may be limited because the Part B drug payment system is not structured to facilitate competition among brand products with similar health effects. In addition, demand for pharmaceutical products may be relatively unresponsive to price changes since many patients do not bear the full cost of the product because of third-party insurance and because these products could serve clinical needs for which alternative treatments do not exist. Because competitive markets for these products are often lacking, placing a constraint on how much Medicare’s ASP + 6 percent payment rate can increase over time would be a safeguard for the Medicare

program and beneficiaries to ensure that Medicare payment rates for existing Part B drugs do not grow rapidly. In addition, some contend that a limit on growth in Medicare’s ASP + 6 percent payment rates would make payment for Part B drugs more consistent with payment for other Part A–covered and Part B–covered services.

At least two approaches exist for implementing an ASP inflation limit: a manufacturer rebate and a limit on provider payment rates. These two approaches differ in terms of which entity bears financial risk for price increases. Under a rebate approach, the manufacturer bears the financial liability if the price of its drug rises higher than an inflation benchmark. Under the payment-limit approach, providers would bear the financial liability for ASP growth greater than inflation. The two approaches also differ in the administrative work required of CMS to implement the policy. A provider payment limit would require fewer administrative resources than a rebate because CMS would not have to calculate and collect rebate payments. Although both approaches have merit, the Commission has chosen to focus on a rebate approach because it results in the manufacturer rather than the provider assuming financial risk for price increases.

The structure of an ASP inflation rebate would include the following elements. A manufacturer of a Part B drug would be required to pay Medicare a rebate if its drug’s ASP (weighted across all NDCs for the manufacturer’s drug) exceeded the inflation-adjusted ASP for the billing code.<sup>27,28,29</sup> For each unit of Medicare use of the manufacturer’s product, the manufacturer would pay Medicare a rebate that equals the difference between the manufacturer’s actual ASP and the inflation-adjusted ASP for the billing code.<sup>30</sup>

Rebates would be shared with beneficiaries by reducing beneficiary cost sharing for drugs that triggered a rebate. The cost-sharing amount for a drug billing code would be reduced when the ASP increased faster than inflation (to the level it would have been if ASP had grown at the same rate as inflation). This cost-sharing reduction would occur up front, with Medicare increasing its payment to the provider to make up the difference. The Medicare program would then receive rebates from the manufacturer afterward and keep the full amount of the rebate. The net result would be that the beneficiary would realize roughly 20 percent of the rebate through lower cost sharing and the program would realize 80 percent (i.e., total rebates minus the additional amount the program paid the provider to make up for the reduced beneficiary cost sharing).<sup>31</sup>



The provider's add-on payment (the 6 percent) would also be based on the inflation-adjusted ASP. Under this approach, the provider's payment for a drug that triggers a rebate would be 100 percent of the actual ASP plus 6 percent of the inflation-adjusted ASP. This policy would be a safeguard to ensure that rapid price increases for a particular product do not translate into large increases in provider add-on payments.

A Medicare inflation rebate policy would exempt certain Part B drugs and certain Medicare use from the rebate. Low-cost drugs—those with an annual cost per user of less than a specified threshold (e.g., \$100)—would be exempt from the rebate policy. With a low-cost drug, a significant percentage increase would be of less concern because it would constitute a relatively small price increase in dollar terms (e.g., a 10 percent increase in ASP for a \$20 drug is \$2). Excluding low-cost products from the policy would also reduce CMS's administrative work and target the policy toward products for which rapid price increases would have the largest impact.<sup>32</sup> Large price increases have occurred among some low-cost generic drugs, so low-cost drugs would be exempt from the ASP inflation rebate policy only as long as they continued to remain low cost.

Manufacturers would also be exempt from paying an ASP inflation rebate on Medicare Part B utilization that is already subject to an inflation discount. Under the Medicaid rebate program and the 340B program, manufacturers pay rebates to states and offer discounted prices to 340B hospitals that incorporate an inflation rebate. To ensure that manufacturers did not pay multiple inflation discounts on the same utilization, manufacturers would be exempt from paying a Medicare inflation rebate on use subject to a Medicaid rebate or 340B discount. This exemption would be similar to current policy in which the same utilization cannot be subject to both a Medicaid rebate and a 340B discount under those two programs.

Some stakeholders have expressed concern that an ASP inflation limit might lead manufacturers to leave the market because they would not be able to increase the price of their product substantially for the portion of their business covered by Medicare Part B, resulting in a product shortage. This potential concern might be most applicable to low-cost drugs where a manufacturer might decide it is not worth it to make the product any longer for a low price. The exemption of low-cost drugs from the Medicare inflation rebate should alleviate such concerns. Some stakeholders have also expressed concern that an ASP inflation rebate might adversely affect a

manufacturer of a drug in short supply (for reasons such as production problems, for example) if a manufacturer wished to increase the price in conjunction with bringing more product to market. The exemption of low-cost drugs from the rebate policy would alleviate this concern for those drugs. With respect to higher cost drugs that are in short supply, policymakers could consider creating a process to permit the Secretary to exempt such products from the ASP inflation rebate on a case-by-case basis. In developing an exceptions process, it would be important to prescribe the limited circumstances under which an exception could be granted so that the policy did not create unintended incentives for shortages.

To operationalize an inflation rebate policy, an inflation benchmark would need to be selected. One option is to use the same inflation benchmark used in the Medicaid rebate program, which is the CPI-U. Other benchmarks could also be evaluated. There are several inflation benchmarks related to drugs (e.g., consumer price index for prescription drugs and producer price index for pharmaceutical preparations); however, these indexes largely capture trends in drug prices established by manufacturers, so it would undermine the policy objective to use them to limit ASP growth. Another option would be to use a producer price index for wholesale distribution of nondrug medical supplies, with smoothing to address volatility that may be present with this type of index. In choosing a benchmark, one principle that could be considered is that the inflation benchmark for Part B drug manufacturers be no greater than the typical payment updates received by other providers in the Medicare program, particularly physicians and hospitals that purchase these drugs.

Reduced spending from an inflation limit would likely come mostly from existing products, while manufacturers of new products that launched after the policy was implemented might respond by increasing their launch prices to partly or fully offset the inflation-limit policy affecting their products. The extent to which manufacturers of new products would be able to fully offset the inflation limit for their products by setting a higher launch price would depend on competitive dynamics. For example, a new breakthrough product might be able to increase its launch price with minimal constraints. In contrast, the manufacturer of a drug with available alternatives might take into account how its launch price would be viewed relative to competitor products already on the market and might be less inclined to raise the launch price to fully offset the inflation limit policy.

## **Consolidated billing codes for a reference biologic and its associated biosimilars**

To spur price competition and pay similar rates for similar products, the Commission supports giving the Secretary the authority to create consolidated billing codes that would assign a reference biologic and its biosimilars to the same billing code. Elements of such a policy would include using the FDA's approval process for biosimilars established by the Biologic and Price Competition and Innovation Act of 2009 to determine what products to group together. The Commission is also interested in the use of broader consolidated billing to spur competition among products with similar health effects.

Within the current ASP payment system, competition is maximized when products that result in similar health effects are assigned to the same billing code—a consolidated billing code—and paid according to the volume-weighted ASP of all products assigned to the code. The current ASP payment system assigns consolidated billing codes to:

- generic drugs along with their associated brand drug. Because of the single billing code and the low research and development costs for generic drugs, Medicare payment rates for drugs that become generic generally decline substantially over time (Medicare Payment Advisory Commission 2010).
- all biosimilar products associated with a given reference biologic. However, unlike generic drugs, biosimilars are not assigned the same code as the reference biologic.

The current ASP payment system does not spur price competition between the reference biologic and its associated biosimilars because the reference product is assigned to one billing code and its biosimilars are assigned to a different billing code. CMS has stated its lack of statutory authority to group the reference biologic and its biosimilars in a single billing code (Centers for Medicare & Medicaid Services 2015). Likewise, the structure of the ASP payment system—with most single-source drugs and most biologics (excluding biosimilars) each being paid under its own ASP rate under separate billing codes—does not promote price competition among products with similar health effects.

The Commission has held that Medicare should pay similar rates for similar care. With respect to the reference biologic and its biosimilars, this principle warrants that

Medicare use a consolidated billing code when paying for these products. The pricing behavior exhibited by the manufacturers of currently available reference biologics and biosimilar products—the ASPs for the two currently available reference biologics have increased despite the availability of their biosimilars, and Medicare's initial payment rate for one of the biosimilars was higher than the reference biologic's rate—suggests consolidated billing codes would spur price competition among these products.

Beyond grouping a reference biologic with its biosimilars, the Commission is interested in the use of broader consolidated billing within the current ASP payment system to maximize competition among products with similar health effects. The text box (pp. 54–55) provides two case studies demonstrating greater competition when Medicare has assigned drugs with similar health effects to a single billing code compared with payment for these drugs when each was under its own separate billing code. Some issues associated with using such a policy more broadly for groups of drugs with similar health effects and groups of biologics with similar health effects are discussed in the text box (pp. 50–52). We encourage the Secretary to conduct research that examines the potential for these broader groupings of Part B products with similar health effects.

### **Creating consolidated billing codes that group a reference biologic with its biosimilars**

Under this policy, the Secretary would have the authority to assign a common billing code to group a reference biologic and its biosimilars, resulting in a single rate paid for all products billed under that code. By contrast, under current ASP policy, the reference biologic has its own billing code and is paid 106 percent of its own ASP. All biosimilar products associated with a particular reference product are grouped together in a single billing code (separate from the reference biologic) and receive a payment equal to 100 percent of the weighted average ASPs for the biosimilar products plus a constant dollar add-on equal to 6 percent of the reference product's ASP.<sup>33,34</sup>

Grouping the reference biologic and its biosimilars together under one billing code and paying all of them the same rate would be expected to generate greater price competition than using two separate codes for these products. Reference biologics receive patent protection and 12 years of exclusivity before a biosimilar can enter the market, during which time the reference biologic faces little price competition. Once the patent

**TABLE  
2-4**

**Use of Zarxio, the biosimilar for Neupogen, has increased since its launch**

	Total Medicare payments (in millions)	Share of total spending		Total units furnished (in millions)	Share of total units	
		Neupogen (reference biologic)	Zarxio (biosimilar)		Neupogen (reference biologic)	Zarxio (biosimilar)
2014						
q1	\$36.0	100%	N/A	37.3	100%	N/A
q2	38.0	100	N/A	38.9	100	N/A
q3	36.8	100	N/A	37.7	100	N/A
q4	33.9	100	N/A	35.0	100	N/A
2015						
q1	32.3	100	N/A	33.2	100	N/A
q2	33.4	100	N/A	34.5	100	N/A
q3	32.3	99.9	0.1%	33.0	99.9	0.1%
q4	30.7	97.3	2.7	31.5	97.2	2.8
2016						
q1	30.1	89.5	10.5	30.8	89.1	10.9
q2	30.7	76.7	23.3	31.4	76.0	24.0
q3*	29.0	68.4	31.6	31.0	65.4	34.6

Note: N/A (not available). "Total Medicare payments" includes beneficiary cost sharing and deductibles.  
\*Spending and utilization for the third quarter of 2016 is preliminary based on Medicare claims available week 9 of 2017.

Source: Acumen analysis of 100 percent Medicare claims data for physicians, suppliers, and outpatient hospitals.

and exclusivity periods elapse, competitive biosimilar manufacturers are able to enter the market and produce a similar product at lower development cost compared with the reference biologic. Under a single payment rate, the reference product and its biosimilars would all face the same incentive to compete based on price and quality and generate the best price for beneficiaries (who are liable for 20 percent cost sharing for Part B drugs) and taxpayers. The effect of including the reference product and biosimilars under a single billing code was considered by the Congressional Budget Office in 2008 when it estimated that an abbreviated approval process for biosimilars would generate more savings if the reference product and biosimilars were assigned to the same Medicare Part B billing code rather than assigning each product a separate billing code (Congressional Budget Office 2008).

Since 2015, manufacturers have launched two biosimilars in the United States. The first biosimilar is Zarxio (filgrastim-bflm), a granulocyte-colony stimulating factor used to manage certain side effects of chemotherapy,

including infection and neutropenic (low white blood cell) fevers. It was launched in September 2015 after the FDA approved it in March 2015 for all of the indications (at that time) of its reference biologic, Neupogen (filgrastim).<sup>35</sup> Table 2-4 shows that since its launch, use of Zarxio among Medicare beneficiaries has increased. As a share of total units furnished, use of Zarxio increased between the fourth quarter of 2015 and the third quarter of 2016 from about 3 percent to nearly 35 percent.<sup>36</sup>

The second biosimilar is Inflectra (infliximab-dyyb), a targeted immune modulator used to treat certain autoimmune diseases including rheumatoid arthritis. Inflectra was launched in the United States in late November 2016 after the FDA approved it in April 2016 for all of the indications of its reference biologic, Remicade (infliximab). Medicare claims data are not yet available to quantify Medicare beneficiaries' use of Inflectra.

Price competition under a consolidated billing code would likely increase as the number of available

## Creating consolidated billing codes for single-source products with similar health effects

**B**roader consolidated billing (beyond a reference biologic and its biosimilars) for single-source products (i.e., single-source drugs and reference biologics) with similar health effects could improve competition and thus achieve lower prices for Part B products. Because Medicare pays for each of these products under its own billing code based on its own average sales price (ASP), there is less pressure for price competition among these products. According to researchers, competition between two or more brand-name manufacturers marketing drugs in the same class does not usually result in substantial price reductions (Kesselheim et al. 2016). Like the combined billing code for a reference biologic and its biosimilars, combining single-source products under a single payment code essentially would set the payment amount based on the volume-weighted ASP for all products included in the single payment code.<sup>37</sup>

Presented below are examples of groups of competing products, with each product paid under a separate billing code based on its separate ASP. Five of the products listed below are among the top 10 Part B drugs as measured by total 2015 expenditures (Table 2-1, p. 38).<sup>38</sup> For each group, we have highlighted the three leading products as measured by total 2015 Part B expenditures and the changes in each product's ASP during the most recent five-year period for which data are available (April 2012 through April 2017). The ASPs for nearly all of the products listed below have either remained the same or increased during this five-year period.

- Erythropoiesis-stimulating agents (ESAs) are biologics used to stimulate production of red blood cells. In 2015, Part B spending for these products totaled nearly \$600 million. The products in this group include epoetin alfa (Procrit/Epogen) and darbepoetin alfa (Aranesp). Between April 2012 and April 2017 (the most recent five-year period data are available), the ASPs for Procrit/Epogen and Aranesp increased at an average annual rate of 6.9 percent and 3.4 percent, respectively. In 2015, mean annual payment per beneficiary for Procrit/Epogen and Aranesp was \$3,200 and \$4,800,

respectively. The launch of a new single-source ESA, epoetin beta (Mircera), in 2015 has resulted in increased competition and shifts in the use of ESAs covered under the dialysis prospective payment system.<sup>39</sup>

- Anti-vascular endothelial growth factor (anti-VEGF) agents are biologics used to treat wet age-related macular degeneration and certain other eye conditions. In 2015, Part B spending for these products totaled nearly \$3 billion. The products in this group include ranibizumab (Lucentis) and aflibercept (Eyelea). Price competition between Lucentis and Eyelea has been very limited: Between April 2012 (when ASP data became available for Eyelea) and April 2017, Eyelea's ASP has remained essentially unchanged (from \$980.50 per unit to \$980.14 per unit, respectively) while Lucentis's ASP has declined modestly (1.3 percent per year). In 2015, mean annual payment per beneficiary for Lucentis and Eyelea was \$9,500 and \$10,000, respectively.
- Targeted immune modulators are biologics used to treat immunologic diseases including rheumatoid arthritis, Crohn's disease, and certain other conditions. In 2015, Part B spending for these products totaled \$2.5 billion. Products in this group include infliximab (Remicade) and its biosimilar (Inflectra), abatacept (Orencia), and rituximab (Rituxan). Between April 2012 and April 2017, the ASPs for Rituxan, Remicade, and Orencia increased by 5.0 percent, 6.1 percent, and 16.7 percent per year, respectively. In 2015, mean annual payment per beneficiary for these three products ranged from \$21,200 to \$22,800.
- Leukocyte growth factors (LGFs) are biologics that stimulate the proliferation and differentiation of normal white blood cells. In 2015, Part B spending for these products totaled \$1.4 billion. The products in this group include filgrastim (Neupogen) and its biosimilar (Zarxio), pegfilgrastim (Neulasta), and tbo-filgrastim (Granix). Between April 2012 and April 2017, the ASPs for filgrastim and

*(continued next page)*

## Creating consolidated billing codes for single-source products with similar health effects (cont.)

pegfilgrastim (the LGFs that have been available since 2012) increased at an average annual rate of 3.0 percent and 8.4 percent, respectively. In 2015, mean annual payment per beneficiary for Granix, Neupogen, and Neulasta was \$2,000, \$3,000, and \$12,800, respectively.

- Immune globulins are for the treatment of primary humoral immunodeficiency, idiopathic thrombocytopenic purpura, and chronic inflammatory demyelinating polyneuropathy. In 2015, Part B spending for these products totaled \$1.3 billion. The products in this group include Gamunex-C/Gammaked, Gammagard liquid injection, and IVIG Privigen. Between April 2012 and April 2017, the ASP for Gamunex-C/Gammaked decreased by 2.0 percent per year, while the ASPs for the remaining products increased by 0.1 percent and 2.1 percent, respectively. In 2015, mean annual payment per beneficiary for these products ranged from \$20,200 to \$26,000.

Among the products that are not in the group of the Part B highest expenditure products are additional examples of products that are competitors and are each paid under separate billing codes based on their separate ASPs:

- Luteinizing hormone-releasing hormone agonists for prostate cancer. In 2015, Part B spending for these products totaled \$302 million. The products in this group include luprolide acetate suspension (Lupron), goserelin acetate implant (Zoladex), and triptorelin pamoate (Trelstar). Between April 2012 and April 2017, the ASPs for each of these products increased, ranging from 0.1 percent per year for Lupron to 15.1 percent per year for Zoladex. In 2015, mean annual payment per beneficiary for these three products ranged from \$1,300 to \$2,000.
- Viscosupplements in which hyaluronate is used to treat osteoarthritis of the knee. In 2015, Part B spending for these products totaled about

\$405 million. The products in this group include a high-molecular-weight form of hyaluronic acid (Orthovisc), hylan G-F-20 (Synvisc and Synvisc One), and sodium hyaluronate (which is a combined billing code for the brand-name products Hyalgan and Supartz). Between April 2012 and April 2017, the ASP for Synvisc/Synvisc One increased by 0.3 percent per year while the ASPs for Hyalgan/Supartz and Orthovisc decreased by 0.5 percent and 1.6 percent per year, respectively. In 2015, mean annual payment per beneficiary for these three products ranged from \$500 to \$900.

- Botulinum toxins, which are used in the treatment of various focal muscle spastic disorders and excessive muscle contractions, such as dystonias, spasms, and twitches. In 2015, Part B spending totaled \$278 million. Products in this group include onabotulinumtoxinA (Botox), rimabotulinumtoxinB (Myobloc), and incobotulinumtoxinA (Xeomin). Between April 2012 and April 2017, the ASP of Botox, which accounted for most of the spending for botulinum toxins (93 percent), increased by 1.6 percent per year. In 2015, mean annual payment per beneficiary for these three products ranged from \$1,600 to \$2,100.

In 2015, Medicare spending for all the products in the above-listed eight therapeutic groups totaled \$9.5 billion. In addition to the groups of products listed above, there are other examples of groups to consider under a broader consolidated billing code policy.

An issue to be considered regarding broader consolidated billing (beyond a reference biologic and its biosimilars) is what criteria CMS would use to determine when products should be grouped together and when they should retain their separate billing codes. For example, it could consider the potential effects on access to care, program spending, and future research on drugs in the category. CMS would also need to develop a process to identify groups of products that achieve comparable clinical outcomes. Some

*(continued next page)*

## Creating consolidated billing codes for single-source products with similar health effects (cont.)

stakeholders have raised concerns about the feasibility of Medicare defining groups of drugs and groups of biologics with similar health effects.

To address this concern, CMS could solicit input from clinical experts and a wide range of stakeholders, including beneficiaries and the public. As part of this process, CMS could seek a technology assessment from groups with clinical expertise, including the Drug Effectiveness Review Project at the Pacific Northwest Evidence-based Practice Center and the Agency for Healthcare Research and Quality's (AHRQ's) Technology Assessment Program. For example, AHRQ sponsored a 2015 technology assessment that reviewed evidence on the effectiveness of hyaluronic acid in the treatment of joint disease of the knee (Agency for

Healthcare Research and Quality 2015). CMS could also seek input from pharmacy benefit managers, commercial health plans, and other such entities that have grouped therapeutically similar single-source drugs and therapeutically similar single-source biologics to develop their coverage and payment policies (Aetna 2017, CVS Health 2016). Once the Part B Drug Value Program (DVP) (a voluntary, market-based alternative to the ASP payment system for physicians and hospital outpatient departments) is in place, CMS could also seek guidance from DVP contractors. Any process for seeking clinical expertise and stakeholder input would need to be carefully designed to avoid conflicts of interest, give the public adequate notice and opportunity for comment, and allow for decisions to be reconsidered as clinical evidence evolves. ■

biosimilars associated with a reference biologic increased. As of October 2016, the FDA had reviewed at least one biosimilar application for a second biosimilar for Remicade and a second biosimilar for Neupogen (Truven Health Analytics 2016).<sup>40</sup>

### **Under separate codes, price competition between a reference biologic and its biosimilar is not maximized**

Two examples of the pricing behavior exhibited by the manufacturers of currently available reference biologics and biosimilar products (biosimilars Zarxio and Inflectra and their respective reference biologics Neupogen and Remicade) suggest that putting the reference biologic and its biosimilars in the same billing code would generate even more price competition than under the current policy of assigning each product a separate billing code. The ASPs for both reference biologics have increased despite the availability of their biosimilars, and Medicare's initial payment rate for one of the biosimilars was higher than the reference biologic's rate:

- Since the launch of its biosimilar Zarxio, the ASP for the reference biologic Neupogen has modestly increased, despite price reductions for Zarxio.
- During the two calendar quarters since its launch, the WAC-based payment rate for the biosimilar Inflectra

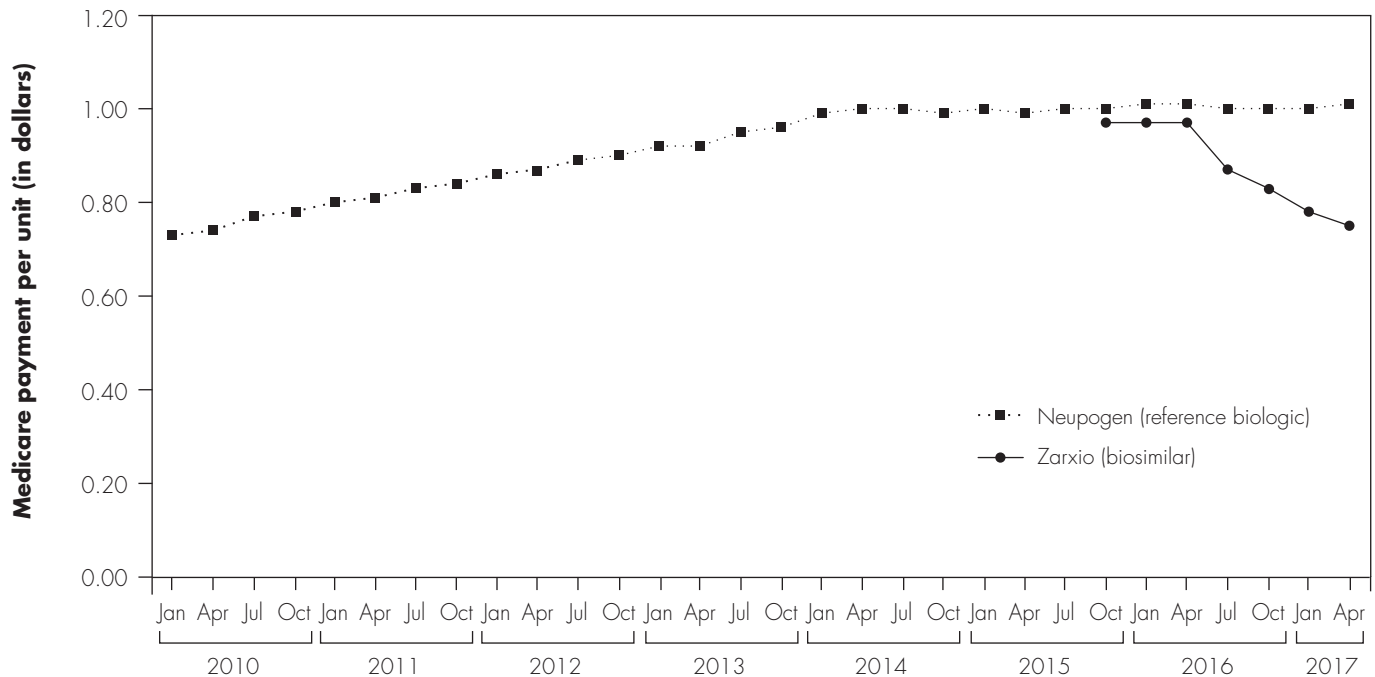
has been higher than the payment rate for its reference biologic Remicade. During this period, the payment rate of the reference biologic increased.

Since its launch, biosimilar Zarxio's payment rate has been lower than that of its reference biologic, Neupogen. Initially, in October 2015, Zarxio's payment rate was 3 percent lower than Neupogen's rate. By April 2017 (the most recent ASP data available), Zarxio's payment rate was 25 percent lower than Neupogen's rate. During this period, Zarxio's payment rate declined by 22 percent while Neupogen's payment rate increased by 1 percent (Figure 2-3).

In contrast, biosimilar Inflectra's initial payment rates during the first two calendar quarters of 2017 were higher than the ASP rate of its reference biologic, Remicade, by 22.0 percent and 17.2 percent, respectively (Table 2-5). During this period, Remicade's ASP increased by 4.1 percent. If Inflectra and Remicade were in a consolidated billing code in the first two quarters of 2017, Medicare would have paid for both products based solely on Remicade's ASP-based rate, which would have reduced the payment rate for Inflectra by 18.0 percent and 14.7 percent, respectively. That is, under a consolidated billing code policy, Medicare's payment rate would be based

**FIGURE 2-3**

**Medicare’s payment rate for the biosimilar Zarxio has been lower than its reference biologic, Neupogen**



Note: Zarxio was launched in the United States in September 2015. The first two calendar quarters of Zarxio’s payment were based on wholesale acquisition cost plus 6 percent. Thereafter, Zarxio’s payment is based on average sales price (ASP) plus 6 percent. During this period, Granix was launched in the United States in November 2013. Granix is, like Neupogen and Zarxio, a granulocyte-colony stimulating factor.

Source: CMS’s ASP quarterly pricing files, 2010–2017.

solely on ASP data (not on WAC data). In contrast, under current policy, the initial payment rate for the biosimilar Inflectra, like other new products assigned to a new billing code, is based on its WAC because ASP data for new products are not available for nearly three calendar

quarters to allow time for manufacturers to report sales data and CMS to calculate an ASP.

Although biosimilars offer potential savings from the reference product’s price, the amount of savings is

**TABLE 2-5**

**Medicare’s payment rate for the biosimilar Inflectra is greater than its reference biologic, Remicade, and the payment rate for Remicade continues to grow**

	Medicare’s payment rate per unit				
	2010 q1	2012 q1	2015 q1	2017 q1	2017 q2
Remicade (reference biologic)	\$58.66	\$62.68	\$74.11	\$82.22	\$85.59
Inflectra (biosimilar)	N/A	N/A	N/A	100.31	100.31

Note: q (quarter), N/A (not available). Inflectra was launched in the United States in November 2016. The first two calendar quarters of Inflectra’s payment were based on wholesale acquisition cost plus 6 percent. Remicade’s payment was based on average sales price (ASP) plus 6 percent for the period indicated.

Source: CMS’s ASP quarterly pricing files, 2010–2017.

## Case studies of Medicare promoting competition by assigning drugs to a single billing code

Because most products have their own billing code, the structure of the average sales price (ASP) payment system does not promote the strongest price competition among single-source products for which there are therapeutic alternatives. The following two case studies show that when Medicare assigned products to the same billing code, more price competition was generated among products than when each product was assigned to its own billing code.

### Case Study 1: Competition between drugs with similar health effects when paid for under a single billing code

Between July 1, 2007, and March 31, 2008, CMS established a single—that is, a consolidated—payment code for levalbuterol, a single-source drug, and albuterol, a multiple-source drug with generic versions. Between January 2005 and January 2007, preceding the establishment of the new code, the ASP for the single-source drug (levalbuterol) increased by 4 percent per year, while the ASP for the multiple-source

drug (albuterol) remained flat (Table 2-6). Under the consolidated billing code, Medicare's payment rate declined from \$0.53 per unit (third quarter 2007 ASP plus 6 percent) to \$0.44 per unit (first quarter 2008 ASP plus 6 percent).<sup>41</sup> The Medicare, Medicaid, and SCHIP Extension Act of 2007 reestablished separate codes for these products starting in the second quarter of 2008 and calculated each product's payment rate based on the lower of (1) the volume-weighted average of 106 percent of the ASP for both drugs or (2) the payment rate based on 106 percent of the ASP for the specific drug.

The coding changes resulted in shifts in Medicare utilization for both products. According to the Office of Inspector General, when each product was billed under its own code between January 2005 and June 30, 2007, use of albuterol (the less costly product) decreased while use of levalbuterol increased (Office of Inspector General 2009). By contrast, when both products were billed under the same code between the July 2007 and March 2008 dates, use shifted from levalbuterol (the more costly product) to albuterol (Office of Inspector General 2009).<sup>42</sup>

(continued next page)

**TABLE  
2-6**

**Payment for two drugs using a consolidated billing code**

	2005	2006	2007			2008				2009	
	q1	q1	q1	q2	q3	q4	q1	q2	q3	q4	q1
Combined payment code				\$0.53	\$0.42	\$0.44					
Separate payment code											
Albuterol	\$0.07	\$0.06	\$0.07	\$0.08			\$0.04	\$0.04	\$0.04	\$0.04	\$0.04
Levalbuterol	\$1.28	\$1.34	\$1.39	\$1.54			\$0.28	\$0.17	\$0.21	\$0.24	

Note: q (quarter). Albuterol is unit dose, 1 milligram. Levalbuterol is unit dose, 0.5 milligram. Between the first quarter of 2005 and the second quarter of 2007, Medicare payment was based on average sales price (ASP) plus 6 percent for each drug. Between the third quarter of 2007 and the first quarter of 2008, payment for the consolidated billing code that included albuterol and levalbuterol was based on the volume-weighted average 106 percent ASP for both drugs. Beginning in the second quarter of 2008, payment for each drug was based on the lower of (1) the volume-weighted average of 106 percent of the ASP for both drugs or (2) the payment rate based on ASP plus 6 percent for the specific drug.

Source: CMS's ASP quarterly pricing files, 2005–2009.



## Case studies of Medicare promoting competition by assigning drugs to a single billing code (cont.)

### Case Study 2: Competition between drugs with similar health effects when paid for under a prospective payment system

Price competition increased between two vitamin D drugs that were previously paid separately when they were paid for under a payment bundle (with a single payment rate assigned to the bundle). Since 2011, Medicare has paid for outpatient dialysis services under a prospective payment system (PPS) that is based on a bundle of services that includes certain dialysis drugs that were previously paid separately. Since the start of

the dialysis PPS, the ASPs for the two leading vitamin D agents each declined between January 2012 and January 2017 by 13 percent per year (Figure 2-4). In contrast, between January 2005 and January 2010, the ASP for both products fluctuated, but overall changed moderately (average annual change of 2 percent to 3 percent over the period). In addition, between 2010 and 2014, per treatment use of the more costly vitamin D drug (paricalcitol) declined while per treatment use of the less costly product (doxercalciferol) increased (Medicare Payment Advisory Commission 2016b).<sup>43</sup> ■

**FIGURE 2-4**

**Price competition increased for vitamin D agents after Medicare implemented dialysis PPS in 2011**



Note: PPS (prospective payment system), ASP (average sales price). CMS implemented the dialysis PPS, which bundled dialysis drugs that were previously separately billable, in January 2011. The vertical line represents drug pricing at the start of the PPS after accounting for a two-quarter ASP reporting lag (i.e., ASPs for the third quarter of 2011 reflect pricing at the start of the PPS in January 2011).

Source: Commission analysis of CMS's ASP pricing files, 2005–2017.

lessened by the substantial price growth that occurs for the reference product in the years before biosimilar entry. During the five-year period before its biosimilar became available, the cumulative price growth for Neupogen

(Figure 2-3, p. 53) and Remicade (Table 2-5, p. 53) was 28.4 percent and 26.1 percent, respectively. While biosimilar Zarxio's payment rate has been discounted relative to Neupogen's rate, the biosimilar's initial

payment rate was greater than the average price for its reference biologic in 2013.

### Implementation issues

There are several issues to consider when implementing consolidated billing codes. One issue is how CMS would determine when products should be grouped together and when they should retain their separate billing codes. For reference biologics and their biosimilars, the FDA's determination that the products are biosimilars would serve as a basis for CMS's decision to consolidate these products.<sup>44,45</sup>

Another key issue is how CMS would set a single payment rate for the reference biologic and its biosimilars that are all assigned to a single payment code. The agency could base its payment according to the volume-weighted ASP of the products assigned to the code. CMS currently uses such an approach when determining the payment rate for generic drugs and their associated brand drug and all biosimilar products associated with, but not grouped with, a given reference biologic.<sup>46</sup>

Under a consolidated billing code policy, a third issue concerns beneficiary access to a particular product for clinical reasons. Under such a policy, the clinician would continue to have the choice to prescribe the product most appropriate for the patient, with Medicare's payment based on the volume-weighted ASP of all products assigned to the code (or some alternative). The Congress could consider allowing the Secretary to provide a very limited payment exception process under which Medicare would reimburse the provider based on the ASP of the higher priced product if the clinician provided justification that the product was medically necessary, such as instances for which there has been documented clinical failure of a particular product. A payment exception process addresses the concern that beneficiary access under a consolidated billing policy could be harmed if some providers were unwilling to supply the higher cost product to a beneficiary for whom the product was a medical necessity.<sup>47</sup> Providers could submit medical justification to the 12 regional Medicare administrative contractors (MACs), and the exception process could be coupled with Medicare's existing appeals process that gives beneficiaries, providers, or their representatives the right to appeal the MACs' coverage and payment decisions.

However, unless carefully designed, a payment exception process could create incentives for the use of higher priced products when the beneficiary's clinical circumstance does

not support an exception. Since the add-on of a higher priced product generates more revenue for the provider than the add-on of a lower priced product, selection of the higher priced product could generate more profit, depending on the provider's acquisition costs for the two products. In addition, direct-to-consumer advertisements could affect provider prescribing (American Medical Association 2015) as well as the promotions (e.g., speaker and consulting fees) offered by some pharmaceutical manufacturers to providers (Fleischman et al. 2016). To minimize such unintended effects, the clinician's payment from Medicare when an exception is granted could be set at the higher cost product's ASP without an add-on payment (i.e., 100 percent of ASP). The Medicare program would pay the provider 80 percent of the ASP of the exception (higher cost) product that was furnished, and the beneficiary would pay the provider 20 percent of the exception (higher cost) product's ASP.

Some stakeholders see advantages to using consolidated billing codes while others see drawbacks. While some industry stakeholders acknowledge that a consolidated billing code policy would result in lower drug prices in the short term, they argue that the subsequent lower prices for the products paid under the policy would reduce the profit potential and return on investment for new products, which would result in the loss of investment capital from venture capitalists (Burich 2016). According to the industry's assumptions, the loss of investment capital would, in turn, decrease the number of manufacturers choosing to enter (or remain in) the biosimilar market, which would decrease the uptake of biosimilars. Ultimately, critics contend, there would be fewer products available, thus leading to less competition and higher prices.

Available objective, transparent data are insufficient regarding the research and development costs of new drugs, biologics, and biosimilars. Given the large market for Part B drugs, it could be argued that development of drugs and biologics is likely to continue, even in the presence of a consolidated billing code policy. With the enormous market that biologics command—in 2015, 8 of the top 10 Part B products ranked by spending were biologics (Table 2-1, p. 38)—biosimilar manufacturers have the opportunity for substantial revenue gains, even with the expected biosimilar discounts that studies estimate range from 10 percent to 50 percent of reference biologics (Mulcahy et al. 2014). In addition, some might argue that biosimilars are in the strongest competitive position with the reference biologic when they are in the same billing code and can compete directly on price. In

Europe, the biosimilar market has grown (with, in some instances, multiple biosimilars in a given therapeutic class) even with the downward pressure on prices. As of March 2017, there are 28 biosimilars available in Europe (European Medicines Agency 2017).

With fewer biosimilars, critics also contend that clinicians would be less likely to prescribe biosimilars because the marketing outreach and education efforts would focus more on the reference biologic than on the available biosimilars. However, assigning all products to the same code would give clinicians the incentive to select the lower cost product when clinically appropriate.

An additional concern is that combined billing codes could have an adverse impact on beneficiary access. Some assert that if a beneficiary needed a particular product paid under a combined billing code and that product were more expensive than the code's other products, the clinician would be unwilling to supply the drug to the beneficiary. While a combined billing code would create incentives to use the lower priced products, the clinician would continue to have the choice to select the product most appropriate for the patient. The payment rate for products paid under a combined billing code currently is based on the volume-weighted average ASP for all the products, not the ASP of the lowest cost product. Under this methodology, the rate paid for a combined code's lower priced products would be higher than if they were paid under separate codes. Thus, clinicians would earn more net revenue than they otherwise would on lower cost products, and that additional revenue could help offset the cost of a higher priced product if needed by a particular patient.<sup>48</sup> A payment exception process might also mitigate any risk of beneficiaries' access being adversely affected.

Some stakeholders are concerned that the use of consolidated billing codes would not permit researchers to conduct safety analyses of Medicare claims data that track a specific product given to a particular beneficiary. The Commission previously stated that if the Secretary concludes that Medicare claims data identifying specific products (i.e., the reference biologic and its biosimilars) could be helpful in supplementing safety analyses such as the FDA's Sentinel System, we believe CMS could develop a way to distinguish these products on claims, such as reporting this information using modifiers (Medicare Payment Advisory Commission 2015a).

Some researchers contend that access to care and the affordability of care should be considered when evaluating

drug pricing proposals and other policy changes (e.g., patent laws) on biomedical innovation. Some have reported that high drug prices adversely affect access to care when patients forgo treatment or are less adherent to a treatment regimen because of high prices (Bach 2015, Walker 2015). Kapczynski and Kesselheim (2016) contend that policies that lower drug prices would improve patient access to care and that the net gains to population health would dwarf possible risks to pharmaceutical innovation. For example, in some European countries, there has been a large volume increase as lower prices for biosimilars (and, in some cases, lower prices for reference products) made the therapies more affordable (IMS Institute for Healthcare Informatics 2016). Nichols (2015) acknowledges the importance of striking the right balance between encouraging innovation—by granting temporary monopoly pricing power—and ensuring affordability by encouraging postmonopoly competition. This researcher goes on to contend that “the [drug] cost problem is sufficiently serious and escalating that it is impossible to believe that we are being well served by the current configuration of innovation encouraging policies and actual pricing choices that specialty drug manufacturers are making” (Nichols 2015).

### **Developing a market-based alternative to the ASP payment system**

The Commission supports the development of a voluntary, market-based alternative to the ASP payment system, calling it the Part B Drug Value Program (DVP). The purpose of such a program would be to obtain lower prices for Part B drugs by using private vendors to negotiate with manufacturers and improve incentives for providers furnishing Part B drugs by making providers accountable for cost and quality through shared savings opportunities. Key elements of this program include its structure, a shared savings component, tools to increase vendors' negotiating leverage (e.g., a formulary and, in certain circumstances, binding arbitration), and a reduction of the add-on in the ASP system.

The DVP would be informed in part by lessons learned from Medicare's experience with the competitive acquisition program (CAP) for Part B drugs. The CAP operated from June 2006 to December 2008. The goal was to remove physicians from the business of buying and billing for drugs and eliminate any financial incentives for prescribing drugs. Under the program, Medicare paid a vendor to supply Part B drugs to physicians who chose to enroll in the program instead of paying the physicians

directly for the drugs they administered. As discussed in our June 2016 report, the CAP was viewed as unsuccessful largely because physician enrollment was low, the vendor had little leverage to negotiate discounts, and Medicare paid the vendor more than ASP + 6 percent for the drugs (Medicare Payment Advisory Commission 2016a). Although the CAP program faced challenges, the concept underlying the program—to create a voluntary alternative to the ASP system using private vendors to negotiate favorable prices and eliminate financial incentives for physicians to prescribe Part B drugs—still has appeal.

The DVP would be designed differently from the CAP to address several issues encountered with the latter program. CAP vendors had little leverage to negotiate discounts with manufacturers because they were required to offer all single-source drugs and biologics. By contrast, DVP vendors would be permitted to use tools (such as a formulary and, in certain circumstances, binding arbitration) to give them greater negotiating leverage with manufacturers. The CAP was also hindered by low physician enrollment; many physicians perceived the process of obtaining drugs directly from CAP vendors as burdensome. Under the DVP, vendors would negotiate prices for Part B drugs, but, unlike the CAP, DVP vendors would not ship product to providers. Providers enrolled in the DVP would continue to buy drugs in the marketplace but at the DVP-negotiated price, and Medicare would reimburse those providers at the same negotiated price. To encourage enrollment in the DVP, providers would also have shared savings opportunities through the DVP while the ASP add-on would be reduced gradually in the ASP system. Savings achieved through the DVP would also be shared with beneficiaries through lower cost sharing and with DVP vendors and Medicare.

A DVP would have the following features:

- voluntary enrollment for physicians and hospital outpatient departments;
- gradual reduction of the ASP add-on in the ASP system to encourage DVP enrollment;
- a small number of DVP vendors, with providers choosing one vendor;
- prices negotiated by DVP vendors (with DVP prices not released publicly);
- drugs purchased by participating providers in the marketplace at the DVP-negotiated price;

- Medicare drug payment to providers at the DVP-negotiated price (with continued payment for drug administration services under the physician fee schedule or outpatient prospective payment system (OPPS));
- shared savings opportunities for providers;
- lower beneficiary cost sharing resulting from lower DVP-negotiated prices;
- an administrative fee paid to vendors by Medicare;
- shared savings opportunities for vendors;
- authority for vendors to use a formulary and other management tools such as step therapy and prior authorization;
- an exceptions and appeals process available to providers and beneficiaries if there is a clinical need for an off-formulary drug;
- a limit on DVP-negotiated prices to no more than 100 percent of ASP;
- binding arbitration available within the DVP as a tool to facilitate vendor and manufacturer price negotiations for high-priced drugs without close substitutes;
- exclusion of DVP prices from ASP calculations; and
- phasing-in of DVP beginning with a subset of drug classes.

#### **Providers' enrollment in DVP would be voluntary**

Each year, physicians and hospitals would have the choice of whether to enroll in the DVP or remain in the ASP system. Providers could not choose which system to enroll in on a drug-by-drug basis. Providers would either choose to participate in the DVP for all drug classes covered by the DVP or remain in the buy-and-bill system for all of those drug classes.

#### **DVP enrollment would be encouraged by reducing ASP add-on in current ASP system**

One of the challenges with the original CAP was that few physicians enrolled. The current 6 percent add-on in the ASP system could make that system more attractive to providers than the DVP. To encourage enrollment in the DVP, the percentage add-on in the ASP system would be reduced and timed to coincide with the target date for starting the DVP.

The reduction of the ASP add-on would begin on that target date, regardless of the DVP's status, to create pressure for the DVP's development and implementation.

Some stakeholders contend that a reduction of the ASP add-on would accelerate the trend toward hospitals' acquisition of physician practices in specialties like oncology. A number of reasons have been cited for physicians' interest in selling to hospitals and hospitals' interest in acquiring physician practices (including availability of 340B discounts, increasing practice costs and reimbursement pressures, site-of-service payment differences, movement toward more integrated models of care, and physician interest in employment rather than ownership). These reasons are both financial and nonfinancial, and the significance of each reason varies across physicians and hospitals. While a reduction of the ASP add-on would be expected to make the ASP system less attractive to some physicians, the DVP would offer physicians an alternative to the ASP system. The DVP removes financial pressure related to drug purchasing and offers physicians new shared savings opportunities, which may encourage physicians to remain independent.

### **The DVP would include only a small number of vendors, with each provider selecting one vendor**

It would be desirable for there to be a small number of national DVP vendors, which would give providers some choice of which vendor to work with while consolidating volume among a small number of vendors to gain greater negotiating leverage. Requiring each participating provider to select one vendor would give the vendor certainty about the size of the population it is negotiating for and make it possible for vendors to use management tools like a formulary.

### **Providers enrolled in the DVP would purchase drugs in the marketplace at DVP-negotiated price**

A DVP vendor's role would be to negotiate prices with manufacturers and make those prices available to providers through a network of distributors and wholesalers (as well as through direct sales from manufacturers in cases where manufacturers use that distribution model). DVP vendors would not ship product to beneficiaries. Instead, providers would order drugs from distributors or wholesalers at the vendor-negotiated price for Medicare fee-for-service (FFS) beneficiaries. Since providers would not know exactly how much of the volume they were ordering would be administered to Medicare FFS beneficiaries, providers could use electronic accounting software to track the amount of product administered to Medicare

FFS beneficiaries. A retroactive reconciliation process could then occur between the provider and distributor or wholesaler after the drugs are administered to confirm the quantity supplied to Medicare FFS beneficiaries and ensure that the price charged for those units was the DVP-negotiated price. The advantage of this approach is that providers would order drugs in the marketplace largely as they do now, without needing to acquire separate inventory for Medicare FFS beneficiaries through a separate entity or to stock their inventory for Medicare FFS beneficiaries separately from product for other patients.

### **Medicare would pay providers for drugs at the DVP-negotiated price**

Providers participating in the DVP would submit a claim to Medicare for Part B drugs administered to beneficiaries, and the Medicare payment rate would be set at the DVP-negotiated price. If the Medicare payment rate were set equal to providers' acquisition costs, this model would eliminate the price spread on drugs and would be expected to give providers less of a financial stake in their prescribing decisions.<sup>49</sup> Under the DVP, physicians and outpatient hospitals would continue to be paid for drug administration services under the physician fee schedule or OPSS. It would be important to review the drug administration payment rates to ensure the inputs used to set those rates were accurate and reflected the cost of administering drugs. Since one aim of the DVP would be to eliminate financial incentives for prescribing Part B drugs, it would be important that manufacturers not be permitted to pay providers rebates based on the amount of volume purchased under the DVP.

### **DVP prices would not be public**

To give DVP vendors greater negotiating leverage, DVP prices would not be public. DVP prices would be known to the government. In addition, the DVP vendor, manufacturers, wholesalers, and distributors that offered products at the DVP's negotiated price and the DVP vendor's provider members would know the DVP-negotiated prices but would not be permitted to disclose that information to others. Beneficiary savings through lower cost sharing would be structured such that the actual DVP-negotiated price for any particular drug would not be revealed.

### **Shared savings opportunities for providers**

Including shared savings opportunities for DVP provider members would have the dual benefit of making the DVP more attractive to providers and improving incentives for provider efficiency.<sup>50</sup> If the DVP led to lower aggregate

costs of Part B drugs, the savings would be shared with providers. This approach would engage providers in managing the total cost of Part B drugs (i.e., the choice of product, the duration of treatment, and the appropriateness of treatment), thereby creating more robust incentives for efficient care than exist under the ASP payment system. Provider eligibility for shared savings could also be contingent on quality performance to avoid incentives for stinting. For example, one option would be to condition providers' receipt of shared savings on their use of clinical guidelines or pathways.

The DVP would be expected to generate savings for products with similar health effects by securing discounts on these products from manufacturers and by giving providers the incentive to use lower cost products where clinically appropriate. Savings would be expected to come from the DVP vendors using tools such as a formulary to negotiate drug prices with manufacturers. For example, for a drug class that includes multiple single-source products with similar health effects, the DVP vendor could secure discounts in exchange for including a manufacturer's product on the formulary. If the price negotiated by the DVP were below what Medicare pays in the ASP system, the savings resulting from the lower price would be shared with providers. In addition, with providers accountable for the total cost of Part B drugs under the DVP, providers would have the incentive to use lower cost products where clinically appropriate, which could also lead to shared savings opportunities.

### **Beneficiaries share in savings**

Beneficiaries receiving drugs under the DVP would save through lower cost sharing. To ensure that DVP prices are not public, beneficiary cost sharing would not be based on the actual DVP-negotiated price for a particular drug. Instead, beneficiary cost sharing would be reduced in a formulaic way that would not reveal the actual price the DVP negotiated for a particular product. Cost sharing could be calculated by estimating the aggregate price that the DVP negotiated (as a percent of ASP) across all DVP drugs and setting beneficiary cost sharing at 20 percent of that amount. For example, if the DVP in aggregate negotiated prices equivalent to 95 percent of ASP across all drugs in the DVP, beneficiary cost sharing could be set at 20 percent of 95 percent of ASP for all DVP drugs.<sup>51</sup>

### **Payment of vendor**

Payment to vendors should be structured in a way that creates incentives for vendors to negotiate discounts

with manufacturers and lower the total cost of Part B drugs. It would be important that the vendor not be paid a percentage of DVP drug spending since that would give vendors an unintended incentive for increased drug prices and spending. Similarly, DVP vendors would generally not be permitted to receive cash payment from manufacturers (e.g., rebates) related to the DVP.<sup>52</sup> Instead, the vendor would be compensated by the Medicare program through an administrative fee and an opportunity for shared savings. Options for how to structure the administrative fee paid to the vendor include a fixed dollar payment, a payment per enrolled provider (possibly varying by provider specialty), or a combination of these approaches. The vendor's shared savings could be similar to provider shared savings, conditioned on whether the DVP reduced the total cost of Part B drugs and whether the vendor engaged in efforts to promote quality or met other performance standards.

### **Medicare shares in savings**

Medicare would share in any savings generated from the DVP, along with beneficiaries, providers, and the vendor.<sup>53</sup> Under the DVP model, Medicare shares in the savings because Medicare's payment rate for the drugs would be set at the DVP-negotiated rate and Medicare would retain a specified share of the resulting savings.

### **Approach for calculating and apportioning shared savings**

In designing the shared savings feature, a crucial piece would be determining how DVP savings were measured. Ideally, a measure of savings would take into account how total Part B drug spending had changed as a result of the DVP, reflecting both changes in price and utilization. It would not be prudent to measure savings based solely on price changes because that could create incentives for choice of an expensive drug with some discount over an inexpensive drug with no discount.

Another important design issue would be how any savings are apportioned among the government, providers, and vendors. Savings would be estimated separately for each DVP vendor (and its provider members). The savings associated with an individual DVP vendor would then need to be distributed among the government, the DVP provider members, and the vendor itself. A threshold could be set for the share of savings retained by the government, such as a fixed share of the savings or an amount that varied by the magnitude of savings.<sup>54</sup> Several approaches could be considered for apportioning the remaining

savings (net of the government's share) to providers and the vendor. One method would be to establish a fixed share of the savings that would go to providers as a whole and to the vendor. In that case, the providers' share of the savings could be apportioned among them based on how the total cost of Part B drugs for the practice or group of practices compared with a benchmark (e.g., the total cost of Part B drugs for providers not participating in the DVP). Alternatively, the providers' share of savings could be apportioned equally across DVP providers with certain adjustments (e.g., by specialty). Another approach would be market based, under which the distribution of savings (net of the government's share) among the vendor and provider members would be determined by the DVP vendor. Because DVP vendors would be competing with one another to attract providers to their membership, vendors would have an incentive to devise a shared savings apportionment approach that was desirable to both providers and the vendor itself.

### **Formulary authority and other management tools**

A key feature of the DVP would be its use of formularies designed by the program's private vendors. Permitting vendors to exclude drugs or biologics from the formulary when other products with similar health effects exist would give them leverage to negotiate lower prices on these products. Criteria would need to be developed to define the terms of an acceptable formulary (e.g., how drug classes are defined, number of drugs required per class, the process and type of input DVP vendors must seek).<sup>55</sup> CMS would oversee the formularies the vendors develop to ensure they meet established standards. Medicare would need to strike a balance between how much flexibility to give DVP vendors versus how prescriptive to be in the requirements. As long as beneficiaries could obtain the medicines they need, flexibility would be beneficial in terms of greater negotiating leverage and less administrative burden for DVP vendors.

In addition to formulary authority, vendors could be permitted to use other management tools. For example, vendors could be permitted to use step therapy and prior authorization. In addition, purchasing tools such as risk-based contracting or indication-specific pricing could be permitted for use by DVP vendors, as long as resulting savings are passed back to the Medicare program.

### **Formulary exceptions and appeals process**

If DVP vendors were allowed to exclude drugs from the formulary, an exceptions process would be needed to give providers and beneficiaries the opportunity to request

coverage of a nonformulary product because of unique aspects of a beneficiary's condition. An exceptions process that involved prior authorization might be ideal in that it would permit providers and beneficiaries to know before administering a nonformulary drug whether an exception would be granted.

If the DVP granted the provider a formulary exception, the provider would obtain the nonformulary drug at the product's DVP-negotiated price. Medicare would pay the provider that price and the usual fee for drug administration services. In this way, a DVP provider member would continue to be paid for drugs under the DVP framework, including nonformulary drugs granted an exception. If the DVP denied the provider's formulary exception request, the provider and beneficiary would have an opportunity to appeal the denial.

### **Limit drug prices under the DVP to no more than 100 percent of ASP**

For a variety of reasons, it is possible that a DVP vendor would not be able to obtain a favorable price for a particular drug. For example, at the outset of the DVP, it may not be clear to a manufacturer how much provider enrollment and product volume a DVP vendor would have, and a manufacturer could decide it was not worth offering a discount to the DVP vendor. One way to ensure that vendors could get at least typical prices for all drugs would be to require drug manufacturers whose drugs are covered under Medicare Part B to offer drugs to DVP vendors at a price no higher than 100 percent of ASP. This requirement would ensure that the DVP vendor could obtain at least typical market prices for all drugs. In addition, requiring that DVP prices be no more than 100 percent of ASP would provide price protection in situations where a nonformulary drug was furnished through the exceptions process—a circumstance under which the DVP vendor would otherwise be unlikely to obtain a favorable price.

### **Arbitration**

For drugs that have generic substitutes, biosimilars, or other single-source drugs that serve as competition, DVP vendors would likely have the ability to negotiate favorable prices. For drugs lacking competition, such as the first drug in a therapeutic class or drugs that offer an advantage over existing drugs, the DVP vendor would likely have little negotiating leverage. In such cases, binding arbitration could be used to encourage drug manufacturers to negotiate with DVP vendors (to avoid going to arbitration) or serve as a means to arrive at an

## Structuring an arbitration process

**A**rbitration is used to settle disputes in a wide range of areas, including labor disputes and international tax disputes. Arbitration has also been used in health care, both domestically and in other countries, to arrive at agreed-upon prices for services and products. For example, New York State employs an arbitration process to settle disputes over prices for certain out-of-network services. In Germany, arbitration is used to set the price of some new drugs as part of the country's effort to lower costs and increase value. While the Secretary would likely go through the rule-making process to establish the arbitration process between Drug Value Program (DVP) vendors and drug manufacturers, the following set of design options are commonly considered when constructing an arbitration process:

- **Type of arbitration**—Two common forms of arbitration are conventional and final-offer arbitration (FOA), which is often referred to as “baseball arbitration”—a moniker earned because of its use to resolve labor disputes in Major League Baseball. Under conventional arbitration, the arbitrator can select any award amount, whereas under FOA, the arbitrator picks the award amount from among the offers made. Conventional arbitration gives disputants an incentive to make extreme offers because arbitrators often “split the difference” between the two offers, whereas FOA, proponents argue, provides an incentive for parties to make reasonable offers. Further, some contend that FOA encourages negotiated settlements because the parties' more reasonable offers might be relatively close together (compared with conventional arbitration) and because both parties want to avoid the risk of the arbitrator choosing the other party's offer.
- **Eligibility for arbitration**—Because formularies create limited pressure on manufacturers to negotiate prices for any of their drugs without competitors, one option would be to limit drugs eligible for arbitration to sole-source drugs that meet some cost threshold. Limiting arbitration to expensive,

sole-source drugs could minimize the number of cases going to arbitration and still create downward pressure on the prices of a subset of drugs that can be very costly to Medicare and beneficiaries. In addition, if an arbitrator sets the price of an expensive, sole-source drug and then a competitor for that drug enters the market while the arbitrated price is still in effect, DVPs could be allowed to add the new drug to their formulary and negotiate prices below the arbitrated price for either drug. Because physicians receive shared savings, they would have an incentive to use the lower cost alternative. This flexibility could help ensure that arbitration does not hinder the ability of market forces to produce lower prices when competition exists.

- **Who goes to arbitration**—While the arbitration process would be established by the Secretary, actual arbitration proceedings would involve DVP vendors and drug manufacturers. Allowing multiple arbitration hearings for the same drug would likely be too costly and time consuming. Therefore, DVP vendors could be allowed to pursue arbitration collectively, or individual DVP vendors could be allowed to initiate an arbitration process and other vendors could be allowed to join that effort. In either option, DVP vendors would choose to go to arbitration voluntarily, while those who choose not to go to arbitration would negotiate directly with the manufacturer. Further, such a process would ensure that manufacturers would face binding arbitration only once for a product in a given time period.
- **Who serves as the arbitrator**—Having a neutral arbitrator with sufficient subject matter expertise is essential to designing an impartial arbitration process. An individual or a panel could serve as the arbitrator. For example, in New York State, disputes are settled by a reviewer with experience in health care billing and reimbursement, in consultation with a physician (New York State Department of Financial Services 2017). Others have suggested that a neutral third party could propose

(continued next page)



## Structuring an arbitration process (cont.)

a slate of arbitrators, with each party having the ability to veto certain arbitrators (Frank and Newhouse 2008). For example, the Government Accountability Office could propose a slate of five arbitrators with specialized expertise and no financial ties to either party. To give both parties input in the process, the drug manufacturer and DVP vendor could each be allowed to strike one arbitrator, leaving a final panel of three arbitrators. A majority decision of the final three arbitrators would constitute a binding decision.

- **Types of issues to be decided by the arbitrator**—Giving the arbitrator a limited number of decisions to make could expedite the arbitration process. For example, the arbitrator could be limited to making two decisions—whether a drug is eligible for arbitration (to the extent that only certain drugs are allowed to go to arbitration) and the net price of a drug for a given period.
- **Arbitration criteria**—Giving an arbitrator a set of criteria on which to select an offer could help ensure consistency among arbitration decisions; expedite the process, as disputants understand what points to argue and the type of information the arbitrator needs; and allow certain priorities to be elevated over others. Criteria could include clinical

benefit compared with existing treatments (which could provide an incentive for manufacturers to pursue high-value drugs), prices of comparable drugs (if any exist), whether the drug addresses specific areas of need (e.g., new antibiotics), and affordability for the Medicare program and beneficiaries.

- **Allowing DVP vendors and providers to share in savings generated by arbitration**—Enrollment in the DVP could be encouraged by including savings generated through an arbitration process when calculating shared savings payments to providers and vendors.
- **Other design choices**—Other design choices include whether to allow the arbitrator to contract with a neutral third party to supplement or evaluate the information contained in the disputants' final offers (e.g., an independent fact finder), what the time frame would be for adjudicating a case, whether the information from the arbitration process is made public, who can call for arbitration, and who pays for arbitration (e.g., cost could be borne by the losing party, which could provide an incentive to make reasonable offers or arrive at a negotiated price before going to arbitration). ■

agreed-upon price if negotiations fail. Arbitration is a process by which two parties agree to accept the verdict of a neutral third party in a dispute—in this case, a dispute over the price of a drug. The two parties entering into arbitration in this case would be the DVP vendor—not CMS—and the drug manufacturer. (See the text box on structuring an arbitration process.)

### **DVP-negotiated prices would not affect ASP**

DVP vendors would be expected to have the most leverage with manufacturers if DVP prices were excluded from ASP. In that case, manufacturers could negotiate low prices with the DVP vendors without DVP discounts leading to lower prices in other lines of business like commercial plans (which often pay based on a percentage

of ASP). In the original CAP program, CMS excluded CAP prices from ASP initially and indicated it would revisit the policy at a later time.

### **Phase in DVP starting with a subset of drug classes**

The complexity of operating the DVP and developing management tools would vary across types of drugs. Phasing in the DVP over time by beginning with a subset of drug classes could address the complexity and create the opportunity to learn from experience going forward. Medicare could choose to phase in the program first with drug classes for which the savings potential seems largest (i.e., drug classes that include multiple products with similar health effects) and implementation seems most straightforward.

Beyond these design issues are additional considerations related to the DVP, including enrollment incentives and the DVP's applicability to Medicare Advantage.

### **Providers' incentive to enroll in the DVP**

An important aspect of designing a DVP would be to give providers an incentive to enroll in the program. When considering DVP enrollment, providers would be expected to consider how their net revenues earned on drugs under the ASP system would compare with the revenues they would receive under the DVP program. Two factors would encourage provider enrollment in the DVP: a reduced add-on under the ASP system and shared savings opportunities available through the DVP.

Reducing the ASP add-on in the ASP system would encourage provider enrollment in the DVP. We would expect providers who are on the higher end of the drug pricing distribution to have the strongest incentive to enroll in the DVP. Although DVP-negotiated prices would not be included in ASP, the movement of providers with relatively high drug acquisition costs out of the ASP system (and effectively out of the data on which ASP is calculated) would be expected to reduce drugs' ASPs (all else being equal). That movement, in turn, may lower the payment rates in the ASP payment system and could encourage more providers to enroll in the DVP. In addition, the gradual reduction of the ASP add-on in the ASP system, which would be timed to coincide with DVP implementation (add-on reduced to 5 percent in year 1, 4 percent in year 2, and 3 percent in years 3 and beyond), would create broader incentives to enroll in the DVP over time.

Shared savings opportunities would also encourage provider enrollment in the DVP. By aggregating volume across providers and using management tools such as a formulary, DVP vendors would likely have leverage to negotiate significant discounts for products with similar health effects. Even for large providers that may receive volume discounts and better than average drug prices, the DVP could be attractive if the vendor were able to negotiate substantial discounts on competitor drugs that could be shared with providers. Phasing in the DVP by focusing on classes of drugs with the most overall savings potential, and thus the most shared savings potential for providers, could help draw attention to the shared savings opportunities for providers and encourage provider enrollment.

In deciding whether to enroll in the DVP, providers would also be expected to consider how the DVP would affect their administrative workload. Some stakeholders suggest

that the administrative processes associated with DVP vendors' use of management tools (e.g., activities such as requesting formulary exceptions or complying with step therapy or prior authorization processes) would dissuade providers from enrolling in the DVP. However, since DVP vendors would be competing with one another for provider enrollment, it would be in vendors' interests to be mindful of providers' concerns about administrative burden and to make their DVP as efficient as possible for providers.

### **The DVP and Medicare Advantage**

The intent of the DVP is to improve Medicare FFS payment for Part B drugs. Whether DVP-enrolled providers should be permitted to purchase drugs at DVP-negotiated rates for their Medicare Advantage (MA) patients is a question that could be explored. MA plans currently have some, but not all, of the tools that DVP vendors would possess. MA plans are permitted to use prior authorization but cannot use a formulary or step therapy for Part B drugs. Permitting providers enrolled in the DVP to purchase drugs at DVP rates for their MA population would be one way to address the limited tools MA plans have for managing Part B drug costs. Another question that could be explored is whether MA plans should be permitted to use a formulary and step therapy to manage Part B drugs—a potential subject for future Commission work.

## **RECOMMENDATION**

**The Congress should change Medicare's payment for Part B drugs and biologicals (products) as follows:**

**(1) Modify the average sales price (ASP) system in 2018 to:**

- **require all manufacturers of products paid under Part B to submit ASP data and impose penalties for failure to report.**
- **reduce wholesale acquisition cost (WAC)-based payment to WAC plus 3 percent.**
- **require manufacturers to pay Medicare a rebate when the ASP for their product exceeds an inflation benchmark and tie beneficiary cost sharing and the ASP add-on to the inflation-adjusted ASP.**
- **require the Secretary to use a common billing code to pay for a reference biologic and its biosimilars.**

**(2) No later than 2022, create and phase in a voluntary Drug Value Program (DVP) that must have the following elements:**

- **Medicare contracts with a small number of private vendors to negotiate prices for Part B products.**

- **Providers purchase all DVP products at the price negotiated by their selected DVP vendor.**
- **Medicare pays providers the DVP-negotiated price and pays vendors an administrative fee, with opportunities for shared savings.**
- **Beneficiaries pay lower cost sharing.**
- **Medicare payments under the DVP cannot exceed 100 percent of ASP.**
- **Vendors use tools including a formulary and, for products meeting selected criteria, binding arbitration.**

**(3) Upon implementation of the DVP or no later than 2022, reduce the ASP add-on under the ASP system.**

## RATIONALE

### Improvements to the ASP payment system

The recommendation would make several immediate improvements to the ASP payment system that together would generate savings for beneficiaries and taxpayers and improve the accuracy of the data on which Medicare's ASP payment rates are established.

Currently, some manufacturers that sell Part B drugs (those that lack a Medicaid rebate agreement) are not required to submit ASP data. Requiring ASP data from all manufacturers would improve the accuracy of CMS's drug prices and help prevent CMS from relying on other, less appropriate prices, such as WACs. As part of this policy, the Secretary could be given the authority to exclude repackagers from reporting, which would reduce administrative burden and avoid issues of double counting.

For the first two to three quarters a new drug is on the market, it is generally paid 106 percent of WAC, a price that does not reflect any available discounts. Reducing the WAC add-on from 6 percent to 3 percent would reduce the current excessive payment rates for WAC-priced drugs and better align the WAC-based and ASP-based payment rates for the same drug. If the ASP add-on is reduced in the future, the add-on percentage for WAC-priced drugs should be further reduced to maintain parity between WAC-priced drugs and ASP-priced drugs.

Increases in Medicare's ASP + 6 percent payment rates are driven by manufacturer pricing decisions, with no limit on how much this payment for a particular product can increase over time. An ASP inflation rebate policy would

provide Medicare and beneficiaries with protection from substantial manufacturer price increases for individual products. The rebate policy would exclude low-cost drugs to reduce administrative burden and exempt utilization already subject to an inflation discount under the Medicaid rebate program and 340B program. To implement a rebate, policymakers would need to select an inflation benchmark (such as the CPI-U, like the Medicaid rebate program, or an alternative), guided by the principle that an inflation benchmark be no greater than the typical payment updates received by providers in other sectors of the Medicare program. A different approach to limiting growth in Medicare's ASP + 6 percent payment rates would be to place a limit on provider payment rates. Although both a rebate approach and provider payment limit approach have merits, the Commission has focused on the rebate approach because it places financial risk for price increases on manufacturers instead of providers.

A consolidated billing code policy that assigned the reference biologic and its biosimilars to a single billing code would be expected to increase price competition among the products. This policy is consistent with the Commission's principle that Medicare should pay similar rates for similar care. In addition to grouping a reference biologic and its biosimilars, the Commission continues to be interested in the use of broader consolidated billing for groups of products with similar health effects. We encourage the Secretary to conduct research that examines the potential for these broader groupings of Part B products with similar health effects.

### Drug Value Program

The DVP would be a voluntary, market-based alternative to the ASP payment system. The program offers the potential for lower prices by permitting private DVP vendors to use tools to negotiate prices with drug manufacturers (e.g., a formulary and, for drugs meeting selected criteria, binding arbitration). The shared savings opportunities available to providers through the DVP would engage providers in managing the total cost of Part B drugs (i.e., the choice of agent, the duration of treatment, and the appropriateness of treatment). This approach has the potential to create more robust incentives for efficient care than exist under the ASP payment system. Savings achieved through the DVP would also be shared with beneficiaries through lower cost sharing and with DVP vendors and Medicare.

## Reduction in the ASP add-on

To encourage provider enrollment in the DVP, the ASP add-on would be reduced in the ASP system. The reduction to the ASP add-on would be timed to coincide with the target date for implementing the DVP (2022). The add-on reduction would begin by that target date, regardless of the status of the DVP, in order to create pressure for DVP development and implementation. The ASP add-on could be reduced gradually, by 1 percentage point per year (i.e., ASP + 5 percent in 2022, ASP + 4 percent in 2023, and ASP + 3 percent in 2024 onward).

## IMPLICATIONS

### Spending

- The Congressional Budget Office estimates that the Commission's recommendation would reduce Medicare program spending by \$250 million to \$750 million in the first year and by \$1 billion to \$5 billion over the first five years relative to current law.

### Beneficiaries and providers

- The recommendation would be expected to generate savings for beneficiaries through lower cost sharing. The policies would not be expected to adversely affect beneficiaries' appropriate access to Part B drugs. The effect of the recommendation would vary across providers. For those providers choosing to remain in the ASP system, ASP add-on payments would be reduced, but the effect on these providers'

net revenues would depend on how manufacturers responded to the policy. Providers that chose to enroll in the DVP would be paid the DVP price without a percentage add-on and would have opportunities for shared savings. For these providers, the DVP could result in an increase or decrease in their revenues, depending on the magnitude of shared savings under the DVP compared with providers' margin on drugs under the ASP system.

## Conclusion

The Commission's recommendation seeks to take a balanced, multipronged approach to improving payment for Part B drugs and achieving savings for taxpayers and beneficiaries. The recommendation includes policies that would improve Part B drug payment through a regulatory approach (by making reforms to the ASP payment system) and through a market-based approach (by developing a voluntary alternative DVP). The Commission's recommendation also seeks balance by including policies that would achieve savings for taxpayers and beneficiaries not just by modifying provider payment rates but also by creating pressure for drug manufacturers to reduce or slow the growth of drug prices (e.g., through consolidated billing codes, an ASP inflation rebate, and DVP vendor tools such as a formulary and binding arbitration). ■

## Endnotes

---

- 1 Medicare Part B covers drugs that are administered by infusion or injection in clinicians' offices and HOPDs if they (1) meet the statutory definition of a drug or a biological, (2) are usually not self-administered, (3) are incident to a clinician's service, (4) are reasonable and necessary for the diagnosis or treatment of an illness or injury, and (5) have not been determined by the Food and Drug Administration to be less than effective.
- 2 By statute, certain vaccines and blood products are paid based on 95 percent of average wholesale price (AWP) instead of ASP + 6 percent. Radiopharmaceuticals billed in physician offices are contractor priced (based on invoice pricing or 95 percent of AWP). Part B–covered home infusion drugs in past years were paid 95 percent of AWP, but beginning in 2017 are paid ASP + 6 percent following the 21st Century Cures Act of 2016.
- 3 Under the OPPIs, in most cases, Medicare pays separately for drugs that have an estimated average cost per day that exceeds a packaging threshold. That threshold (\$110 in 2017) was \$95 in 2015, the period of our data analysis. Payment for drugs with an estimated average cost per day less than the threshold are packaged into payment for other separately payable services on the claim (e.g., drug administration). Beginning in 2014, drugs used as part of diagnostic tests or as supplies in surgical procedures are packaged regardless of their cost.
- 4 The sequester reduces payments providers receive for Part B–covered drugs by 1.6 percent, which results in a net payment equivalent to ASP plus 4.3 percent. Unless otherwise noted, our analysis focuses on the pre-sequester ASP + 6 percent payment rate because that is the rate specified in the Medicare statute for most Part B–covered drugs provided by physicians and suppliers.
- 5 This chapter uses the term *biologic* synonymously with *biological products* or *biologics*, referring to drug products derived from living organisms. (See Chapter 5 of the Commission's June 2009 report for more detail (Medicare Payment Advisory Commission 2009)).
- 6 This estimate of payments for drug administration services includes therapeutic, prophylactic, diagnostic, and intravitreal injections. It also includes infusions of chemotherapy and nonchemotherapy drugs. It excludes certain types of injections such as arthrocentesis injections. In addition, it excludes payment for administration of the three Part B–covered preventive vaccines (which totaled more than \$500 million in 2015).
- 7 Aggregate 2015 Part B drug spending was about \$25.7 billion based on 100 percent claims data for physicians, suppliers, and outpatient hospitals. This amount excludes Part B drug spending for critical access hospitals (about \$600 million) and Maryland hospitals (about \$300 million), which are not paid under the ASP system. It also excludes spending for ESRD facilities, which are mostly paid for Part B drugs through the dialysis bundled payment rate.
- 8 One factor driving spending growth in 2015 was increased spending (over \$900 million) on the vaccine Prevnar 13. A Centers for Disease Control and Prevention advisory committee recommended a one-time vaccination of all adults age 65 and older, which led to substantial utilization of the vaccine in 2015.
- 9 Nonprofit hospitals with high shares of Medicaid and low-income Medicare patients (about one-third of all prospective payment system hospitals) qualify for the 340B Drug Pricing Program.
- 10 Manufacturers calculate ASP based on sales to all purchasers, excluding nominal sales to certain entities and sales that are exempt from the determination of Medicaid best price (e.g., sales or discounts to other federal programs, 340B–covered entities, state pharmaceutical assistance programs, and Medicare Part D plans). The types of discounts that must be netted from ASP include volume discounts, prompt-pay discounts, cash discounts, free goods that are contingent on any purchase requirement, and charge-backs and rebates (other than rebates under the Medicaid program). Bona fide service fees—for example, fees paid by the manufacturer to entities such as wholesalers or group purchasing organizations that are fair market value, not passed on in whole or part to customers of the entity, and are for services the manufacturer would otherwise perform in the absence of the service arrangement—are not considered price concessions for the purposes of ASP.
- 11 Additional factors can create a gap between the average price providers pay for drugs and the ASP used to set the Medicare payment amount. For example, prompt-pay discounts paid by manufacturers to wholesalers (which are anecdotally reported in the range of 1 percent to 2 percent) can create a gap between ASP and provider's acquisition costs because they are subtracted from ASP but are reportedly not fully passed on to purchasers. In addition, more technical issues, such as the treatment of lagged price concessions and bundled price concessions in the ASP calculation, can create a gap between provider acquisition costs for a drug and ASP.
- 12 Prices in the IMS Health Incorporated data reflect all on-invoice discounts and rebates, but not off-invoice rebates. Data for clinics include physician offices, hospital outpatient departments, dialysis clinics, nonhospital surgical centers, and

public health services clinics. The IMS data for clinics include discounted sales to 340B entities. To avoid reflecting 340B prices in our estimates, we focused on data in the top half of the distribution (e.g., the 75th percentile).

- 13 The 11 manufacturers included in the margin analysis included AbbVie, Amgen, Baxalta, Biogen, Bristol-Myers Squibb Company, Celgene, Eli Lilly and Company, Gilead Sciences, Johnson & Johnson, Merck & Co., and Pfizer.
- 14 We note that, when comparing ROAs across different types of industries, the ROA for drug manufacturers is thought to be overstated due to the longer than average lag time between research and development and new product launch (Congressional Budget Office 2006). In addition, the accounting treatment of drug research and development (where research and development investments are counted as expenses instead of capitalized investments) may also distort ROA estimates either upward or downward (Reinhardt 2001).
- 15 Yu and colleagues (2017) compared drug prices in the United States to four countries (Canada, the United Kingdom, Ireland, and Denmark) for a group of manufacturers and estimated that the additional revenue generated by the difference in prices between the United States and other countries was greater than these manufacturers' global research and development spending by about 50 percent.
- 16 As discussed in our June 2016 report, providers' prescribing decisions may depend on a variety of factors (Medicare Payment Advisory Commission 2016a). A number of clinical considerations may influence a provider's choice among therapeutic alternatives (e.g., the product's efficacy for patients with a particular condition or comorbidities and its potential side effects). Financial considerations may also play a role in providers' choice of drugs. Since 6 percent of a higher priced drug generates more revenue for the provider than 6 percent of a lower priced drug, selection of the higher priced drug may generate more profit, depending on the provider's acquisition costs for the two drugs. It is difficult to know whether the percentage add-on to ASP is influencing drug prescribing patterns because few studies have looked at this issue.
- 17 Similar to current law, some sales, such as those to 340B hospitals, would be excluded from the ASP calculations.
- 18 Requiring all Part B drug manufacturers to report ASP data is also complementary to our proposed inflation limit policy since universal ASP reporting helps to ensure that there is the requisite data on all drugs to implement the policy appropriately.
- 19 Excluding repackagers from the reporting requirement is not expected to create access issues because (1) many Part B drugs are not repackaged, and (2) under the current ASP reporting practices, repackagers often do not report their data, and access issues related to this lack of reporting have not been reported.
- 20 In cases where the WAC is unavailable, CMS uses invoice pricing or 95 percent of the average wholesale price under the outpatient prospective payment system.
- 21 Specifically, the drugs selected were among (1) the top 20 highest expenditure Part B drugs in 2014 and (2) those whose earliest year of ASP data was after 2005.
- 22 For the purposes of this section, CMS's *ASP drug pricing files* refers to either the quarterly ASP file or the "not otherwise classified" (NOC) file. If a drug had a payment rate posted on the outpatient prospective payment system's quarterly addendum files before appearing in CMS's ASP or NOC file, this earlier date served as the beginning of the one-year period.
- 23 As an example, OIG presented the case of the Healthcare Common Procedure Coding System code J7321. OIG noted that Part B spent \$67 million on this drug in 2012 and, while the manufacturers reported ASP data, they were not required to do so. If the manufacturers had not reported the data and payments were based on WAC, OIG stated that payments would have been substantially higher because the WACs of the NDCs associated with the drug were 52 percent and 96 percent higher than ASP.
- 24 Because biosimilars are currently assigned a Healthcare Common Procedure Coding System code separate from their reference biologic, an ASP for the first biosimilar to a reference product may not be available for nearly three calendar quarters because of a lag in data reporting. During that period, biosimilars are paid at 106 percent of their WAC.
- 25 The Secretary has the authority to substitute for a product's ASP + 6 percent payment rate the lesser of the widely available market price (WAMP) or 103 percent of the average market price (AMP) if OIG finds that the product's ASP exceeds the AMP or WAMP by a certain threshold (currently 5 percent). (Note that AMP is the weighted average of retail prices for all of a manufacturer's package sizes of a drug, and WAMP is the price that a prudent physician or supplier would pay for a product.) Like ASP, AMP and WAMP are driven by manufacturers' pricing decisions and do not serve as an inflation-limit mechanism.
- 26 We focus on products with spending of at least \$5 million in 2015 because we want to avoid the potential for drugs with substantial price increases but minimal Medicare spending (e.g., less than \$500,000) to skew the analysis.
- 27 The inflation-adjusted ASP for the billing code for a given quarter would be calculated by applying the cumulative rate

- of inflation between a specified base period and that quarter (using a specified measure of inflation like CPI-U, as in Medicaid, or an alternative inflation measure) to the billing code's ASP for the base period.
- 28 Because Medicare pays for Part B drugs based on billing codes, the ASP inflation rebate would be calculated at the manufacturer billing-code level. (By contrast, Medicaid pays for drugs at the NDC level, so the Medicaid inflation rebate is calculated at the NDC level). The ASP inflation rebate would compare each manufacturer's billing-code-level ASP (calculated as a weighted average across all the manufacturer's NDCs) to the inflation-adjusted ASP for the entire billing code. A benefit of this approach is that it promotes equity among manufacturers in multiple-source billing codes (because it ensures that the lower priced manufacturers would pay no rebate or a smaller unit rebate than higher priced manufacturers).
  - 29 Medicare Part B pays for three types of vaccines based on 95 percent of the average wholesale price (instead of 106 percent of ASP), and thus the ASP inflation limit would not be applicable to these products.
  - 30 To operationalize a rebate for multiple-source drugs, utilization data for the different manufacturers' products in the multiple-source billing code would be needed. NDCs could be required to be reported on the claims as a way to identify an individual manufacturer's utilization. If NDCs posed claims processing challenges, the utilization data reported by manufacturers when submitting ASP data could be used to calculate each manufacturer's market share for a multiple-source drug.
  - 31 The intent of this approach—in which beneficiary cost sharing was reduced to 20 percent of 106 percent of the inflation-adjusted ASP and the government increased its upfront payment to the provider to offset a portion of the cost-sharing reduction—is to share rebates to the fullest extent possible with beneficiaries. If there are claims processing challenges with this approach, an alternative would be to set the beneficiary cost sharing at 20 percent of the following: 100 percent of the reported ASP plus 6 percent of the inflation-adjusted ASP. Under this alternative approach, the beneficiary would continue to share in the rebates but to a lesser extent, and the Medicare program would not have to increase its upfront payment to the provider.
  - 32 If an inflation rebate policy applied only to billing codes with an average annual cost per user exceeding \$100, about 36 percent of Part B drug billing codes would be exempt from the policy.
  - 33 To provide CMS the ability to track claims payment and to develop a better understanding of the use of certain biosimilar products, claims for biosimilars are required to include a modifier that identifies the product's manufacturer effective January 1, 2016.
  - 34 In the final rule for payment year 2016, CMS clarified that biosimilars that rely on a reference product's biologics license application will be grouped into the same payment calculation for determining a single ASP payment rate.
  - 35 Subsequently, the FDA approved the reference biologic for one additional indication (increased survival in patients acutely exposed to myelosuppressive doses of radiation) which, as of August 2016, is not yet listed on the biosimilar's label.
  - 36 Use of Neupogen and Zarxio is derived from an analysis by the Commission's contractor (Acumen) that used 100 percent Medicare claims data.
  - 37 In addition, a combined billing code could be assigned to single-source drugs and multiple-source drugs with similar health effects.
  - 38 These five products are aflibercept, rituximab, pegfilgrastim, infliximab, and ranibizumab.
  - 39 Medicare use of Mircera in 2015 and 2016 was chiefly by beneficiaries with end-stage renal disease on dialysis. As stated in our March 2017 report to the Congress, there has been a shift in the use of ESAs (Epoen, Aranesp, and Mircera) under the outpatient dialysis prospective payment bundle. A large dialysis provider announced its intent to have 71 percent of the company's ESA patients (110,000 patients) switched to epoetin beta (from epoetin alfa) by the end of the first quarter of 2016. Our analysis shows that, in 2015 (when the biologic was launched in the United States), 90,000 dialysis patients received Mircera (Medicare Payment Advisory Commission 2017).
  - 40 As of April 2017, the following biosimilars have been approved by the FDA but not yet launched by their manufacturers: Renflexis (infliximab-abda), the biosimilar for Remicade; Amjevita (adalimumab-atto), the biosimilar for Humira; and Erelzi (etanercept-szszs), the biosimilar for Enbrel.
  - 41 Levalbuterol remained a single-source drug for the period shown on Table 2-6 (p. 54).
  - 42 Based on 100 percent Part B claims data for albuterol and levalbuterol, the Commission's analysis showed that albuterol volume (as measured by the number of units furnished to beneficiaries) between the first quarter of 2005 and the second quarter of 2007 declined from 91 percent to 59 percent of total volume of these inhalation drugs.
  - 43 Between 2014 and 2015, per treatment use of both products declined under the dialysis PPS.

- 44 In 2010, the Biologics Price Competition and Innovation Act established a pathway for the approval of biosimilars. Applicants must demonstrate that their product is “highly similar” to the already-licensed biologic with “no clinically meaningful differences” in terms of safety, purity, and potency (Food and Drug Administration 2016).
- 45 If the policy were applied more broadly to groups of single-source products with similar health effects, the Secretary would need to develop a process to identify groups of products that achieve comparable clinical outcomes.
- 46 There are alternative approaches that CMS could consider in determining the payment rate for products assigned to a single payment code, such as basing the payment rate on the product with the lowest ASP.
- 47 Because small changes to manufacturing processes can alter the structure of biologics and their pharmacologic activity, some stakeholders contend that the immunogenicity of biosimilars could vary from their reference products. However, Ebbers and colleagues (2012) found no evidence from clinical trial data or postmarketing surveillance data that switching to and from different biologics (erythropoietins and granulocyte-colony stimulating agents) leads to safety concerns. A recent analysis of the interchangeability of biosimilars authored by employees of the national regulatory agencies of Germany, Finland, the Netherlands, and Norway concluded that switching patients from the original to a biosimilar or vice versa can be considered safe (Kurki et al. 2017). Advocates point to the lack of adverse events in Europe as evidence that biosimilars can be used safely by patients (Madsen 2016). In the United States, there have been no reports in the press of adverse events when Fresenius switched about 110,000 dialysis patients from epoetin alfa to epoetin beta in 2015 and 2016.
- 48 The two-quarter lag in the ASP payment rates also helps to offset the financial effect on providers who might be slower than average to shift toward the lower cost options.
- 49 Whether the sequester should apply to the DVP would need to be considered. Since the intent of the DVP is for providers to be paid their acquisition costs (i.e., the DVP rate), an argument could be made that the sequester should not apply to DVP rates paid to providers. If the sequester applied to the DVP rates paid to providers, providers would be reimbursed 1.6 percent below their acquisition costs for drugs under the DVP.
- 50 CMS has implemented several initiatives, such as accountable care organizations and the Oncology Care Model, that aim to improve the quality and efficiency of Medicare services, including Part B drugs. Whether these programs will lead to changes in Part B drug utilization remains to be seen. Unlike the DVP, these initiatives are not designed to lower the current ASP + 6 percent payment for Part B drugs. Precedent rules would need to be established for allocating shared savings among the DVP and these other Medicare-sponsored initiatives.
- 51 In any given year, the average DVP-negotiated price as a percent of ASP across all DVP drugs in aggregate will not be known until utilization data for those drugs are available after the close of the year. To base the beneficiary’s cost sharing on the aggregate DVP-negotiated price, this price will need to be estimated either using prior-year data or by projecting utilization for the current year.
- 52 There may be innovative purchasing approaches like risk-based contracting or indication-specific pricing in which rebates are the most effective way to operationalize the policy, and, in that case, there may be a benefit to permitting rebates specifically in such circumstances, provided these arrangements are transparent to CMS and the rebates are passed through to the Medicare program.
- 53 Although group purchasing organization (GPO) prices are generally included in the calculation of ASP, Medicare and beneficiaries do not share in GPO savings under the ASP system to the same extent that they could share in savings under the DVP. If GPOs are able to obtain lower than average prices, then GPO prices will lower ASP to some degree, but not fully because they are averaged in the ASP calculation with prices for other purchasers. In contrast, under the DVP, the Medicare drug payment rate would be set at the DVP-negotiated rate. Beneficiaries would pay lower cost sharing based on the lower DVP-negotiated rates. Medicare would also retain a specified share of the savings with the remainder shared with providers and vendors.
- 54 For example, to ensure that providers and vendors find the savings opportunities attractive and are encouraged to participate, the government share of savings could be lower for the first 5 percent of savings and higher for any savings beyond 5 percent.
- 55 It would be important that the formulary development process include the input of physicians, as well as pharmacists and other experts, while nevertheless avoiding conflicts of interest.



## References

---

- Aetna. 2017. Specialty pharmacy clinical policy bulletins. <http://www.aetna.com/products/rxnonmedicare/data/2017/MISC/G-CSF.html>.
- Agency for Healthcare Research and Quality. 2015. *Systematic review for effectiveness of hyaluronic acid in the treatment of severe degenerative joint disease (DJD) of the knee*. Technology assessment report. Rockville, MD: AHRQ. <https://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/id101TA.pdf>.
- American Medical Association. 2015. AMA calls for ban on DTC ads of prescription drugs and medical devices. Press release. November 17. <https://www.ama-assn.org/content/ama-calls-ban-direct-consumer-advertising-prescription-drugs-and-medical-devices>.
- Bach, P. B. 2015. New math on drug cost-effectiveness. *New England Journal of Medicine* 373, no. 19 (November 05): 1797–1799.
- Burich, M. 2016. Potential unintended consequences of CMS' policy for biosimilars reimbursement. <https://www.biosimilardevelopment.com/doc/potential-unintended-consequences-of-cms-policy-for-biosimilars-reimbursement-0001>.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015. Medicare program; revisions to payment policies under the physician fee schedule and other revisions to Part B for CY 2016. Final rule with comment period. *Federal Register* 80, no. 220 (November 16): 70886–71386.
- Congressional Budget Office. 2008. *Budget options, volume 1: Health care*. Washington, DC: CBO.
- Congressional Budget Office. 2006. *Research and development in the pharmaceutical industry*. Washington, DC: CBO.
- Congressional Budget Office. 1996. *How the Medicaid rebate on prescription drugs affects pricing in the pharmaceutical industry*. Washington, DC: Government Printing Office.
- CVS Health. 2016. 2017 Standard formulary list of removals and updates. <http://investors.cvshealth.com/~media/Files/C/ CVS-IR-v3/documents/02-aug-2016/2017-standard-formulary-list-of-removals-and-updates.pdf>.
- Deloitte. 2016. *Measuring the return from pharmaceutical innovation*. London: Deloitte UK Centre for Health Solutions. <https://www2.deloitte.com/uk/en/pages/life-sciences-and-healthcare/articles/measuring-return-from-pharmaceutical-innovation.html>.
- Ebbers, H. C., M. Muenzberg, and H. Schellekens. 2012. The safety of switching between therapeutic proteins. *Expert Opinion on Biological Therapy* 12, no. 11 (November): 1473–1485.
- European Medicines Agency. 2017. European public assessment reports. <http://www.ema.europa.eu/>.
- Fein, A. 2016. Profits in the 2016 Fortune 500: Manufacturer vs. wholesalers, PBMs, and pharmaceuticals. *Drug Channels* blog. June 21. <http://www.drugchannels.net/2016/06/profits-in-2016-fortune-500.html>.
- Fleischman, W., S. Agrawal, M. King, et al. 2016. Association between payments from manufacturers of pharmaceuticals to physicians and regional prescribing: Cross sectional ecological study. *British Medical Journal* 354 (August 18): i4189.
- Food and Drug Administration. 2016. Information on biosimilars. <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/default.htm>.
- Frank, R. G., and J. P. Newhouse. 2008. Should drug prices be negotiated under Part D of Medicare? And if so, how? *Health Affairs* 27, no. 1 (January–February): 33–43.
- IMS Institute for Healthcare Informatics. 2016. *Delivering on the potential of biosimilar medicines*. Parsippany, NJ: IMS Institute for Healthcare Informatics.
- Kapczynski, A., and A. Kesselheim. 2016. Why 'government patent use' to lower drug costs won't stifle innovation. *Health Affairs* blog. July 28. <http://healthaffairs.org/blog/2016/07/28/why-government-patent-use-to-lower-drug-costs-wont-stifle-innovation/>.
- Kesselheim, A. S., J. Avorn, and A. Sarpatwari. 2016. The high cost of prescription drugs in the United States: Origins and prospects for reform. *Journal of the American Medical Association* 316, no. 8 (August 23–30): 858–871.
- Kurki, P., L. van Aerts, E. Wolff-Holz, et al. 2017. Interchangeability of biosimilars: A European perspective. *BioDrugs* 31, no. 2 (April): 83–91.
- Madsen, S. 2016. Biosimilars: Myths and realities in the European experience. Presentation at the St. Petersburg Oncology Forum. June 23. <https://www.youtube.com/watch?v=ZbiZrT7hxrU>.

- Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2016a. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2016b. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2015a. MedPAC comment on CMS's proposed rule on the physician fee schedule and other revisions to Part B, September 8.
- Medicare Payment Advisory Commission. 2015b. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2010. *Report to the Congress: Aligning incentives in Medicare*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2009. *Report to the Congress: Improving incentives in the Medicare program*. Washington, DC: MedPAC.
- Mulcahy, A., Z. Predmore, and S. Mattke. 2014. *Perspective: The cost saving potential of biosimilars in the United States*. Santa Monica, CA: RAND Corporation.
- New York State Department of Financial Services. 2017. Protection from surprise bills and emergency services. <http://www.dfs.ny.gov/consumer/hprotection.htm>.
- Nichols, L. 2015. *What price should we pay for specialty drugs?* Fairfax, VA: Center for Health Policy Research and Ethics.
- Office of Inspector General, Department of Health and Human Services. 2014. *Limitations in manufacturer reporting of average sales price data for Part B drugs*. OEI-12-13-00040. Washington, DC: OIG.
- Office of Inspector General, Department of Health and Human Services. 2009. *Beneficiary utilization of albuterol and levalbuterol under Medicare Part B*. Washington, DC: OIG.
- Reinhardt, U. E. 2001. Perspectives on the pharmaceutical industry. *Health Affairs* 20, no. 5 (September–October): 136–149.
- Truven Health Analytics. 2016. Biosimilar market access. <http://www.firstwordpharma.com>.
- Walker, J. 2015. Patients struggle with high drug prices. *Wall Street Journal*, December 31.
- Yu, N., Z. Helms, and P. B. Bach. 2017. R&D costs for pharmaceutical companies do not explain elevated US drug prices. *Health Affairs* blog. July 28. <http://healthaffairs.org/blog/2017/03/07/rd-costs-for-pharmaceutical-companies-do-not-explain-elevated-us-drug-prices/>.